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NHANES 2015-2016 Laboratory Data Overview

- NHANES 2015-2016 Overview
- 2015-2016 Laboratory Procedures Manual

MEC Operation and Schedule

NHANES collects biological specimens (biospecimens) for laboratory analysis to provide detailed information about participants' health and nutritional status. Eligibility for specific laboratory tests is based on the survey participants' gender and age at the time of screening. The biospecimen collection took place in the mobile examination center (MEC). This included the collecting, processing, storing, and shipping of blood, urine, and other types of specimens. The controlled environment of the MEC allowed laboratory measurements to be performed under identical conditions at each survey location.

The MEC is open 5 days per week; the non-operational days change on a rotating basis so that appointments can be scheduled on any day of the week. Two examination sessions are conducted daily. Participants are randomly assigned to exams in the morning session, or in the afternoon or evening sessions. Participants aged 12 years and older appointed to a morning session are asked to fast for 9 hours. Participant's fasting status is assessed by the MEC phlebotomist prior to the blood draw.

Biological Specimens Collection

The biospecimens collected in NHANES 2015-2016 include:

Blood

Blood was collected from participants aged 1 year and older by a phlebotomist at the MEC. The amount of blood drawn varied by age. Blood was processed and aliquoted into vials for storage in the MEC. The vials were then refrigerated or frozen before transport to laboratories across the United States. Most assays were completed in remote laboratories, except for the CBC and pregnancy tests, which were performed in the MEC. If permission were granted, some specimens were aliquoted into vessels and banked for future studies.

Participants aged 12 and older, who were examined in the morning session and had completed at least a 9-hour fast, were asked to participate in an oral glucose tolerance test (OGTT). After the initial blood draw, they were asked to drink 75 grams of dextrose (10 oz of glucose solution) within 10 minutes. Two hours later, a second blood sample was collected. The inclusion of OGTT provided information on the extent of impaired glucose tolerance, or IGT, and diabetes in the U.S. population.

Urine

In 1999-2014, NHANES had collected urine specimens for all participants aged 6 years and older. Starting 2015, the target age for urine collection was extended to all participants aged 3 years and older in the MEC.

Participants aged 6 and older were asked to provide a full void of urine in the MEC using a specimen cup. The parents/guardians of participants aged 3-5 years were asked to help their children collect a full void of urine in the MEC bathroom using a urine collection container set on the toilet. The date and time of the last urine void, along with the date, time, and volume of the urine specimen collected in the MEC were used to provide a measurement of urine flow rate. The urine specimen was also used: 1) to perform a urine pregnancy test on all female participants aged 12-59 years and menstruating females aged 8-11 years; 2) to aliquot, store, and transport to multiple laboratories for analysis; and 3) to aliquot and bank for future studies.

Oral rinse

An oral rinse was collected and tested for the presence of multiple types of human papillomavirus (HPV). The examining dentist instructed participants aged 14-69 to gargle and swish with mouthwash for 30 seconds and then spit into a specimen container.

Vaginal/Penile swabs

Female and male participants aged 14-59 were asked to self-collect a vaginal or penile specimen using a sterile swab. The vaginal and penile swabs were tested for the presence of multiple types of HPV.

Collection procedures varied based on the specimen types. Please refer to the 2015-2016 Laboratory Procedures Manual for more details.

NHANES Laboratory Setting

Each MEC had a laboratory containing a laminar flow hood, complete blood count (CBC) with 5-part differential analyzer, two centrifuges, a portable balance (scale), refrigerators, and freezers. Each MEC laboratory team included three medical technologists and a phlebotomist. Staff were certified in accordance with guidelines set forth by the American Society for Clinical Pathology. The qualifications for these laboratory staff are described in the component training manuals. All laboratory staff are thoroughly trained to ensure the safety of the laboratory environment. This includes annual training in the following laboratory safety and infection control policies and procedures:

- Occupational Safety and Health Administration (OSHA) Blood borne Pathogen Regulation;
- NHANES exposure control plan;
- Working safely with hazardous chemicals;
- Universal precautions and a set of guidelines for preventing the transmission of blood borne pathogens such as human immunodeficiency virus (HIV) and hepatitis viruses in health care settings; and
- International Air Transport Association (IATA) training for proper shipping dangerous goods.

All staff also completed the requirements for subject privacy and confidentiality, and cardiopulmonary resuscitation training. In addition, all laboratory staff completed component-specific training to learn the standardized NHANES laboratory protocols.

The complete blood count and pregnancy analyses were performed in the MEC laboratory. Other laboratory analyses were conducted off-site. For 2015-2016, 35 laboratories, across the United States, analyzed NHANES specimens.

Automated Data Collection

In the MECs and analytical laboratories, data for the laboratory component were recorded directly into a computerized database. Related questionnaire forms, such as the one assessing fasting status, were also automated. The laboratory data collection and reporting systems were integrated with the main NHANES survey database.

Quality Control Monitoring

The NHANES MEC laboratory has been a Clinical Laboratory Improvement Act (CLIA)-certified laboratory of moderate complexity. Quality assurance and quality control (QA/QC) involved both internal and external surveillance. QA/QC procedures were performed in the MEC, as well as in contract and CDC laboratories. As part of the overall QA process, all collection materials, vacuum sample vials, and storage containers used were initially prescreened for background contamination levels of blood lead, cadmium, selenium, manganese, and mercury; serum copper, zinc, selenium, chromium, and cobalt; and urinary metals, arsenic, iodine, and mercury. EDTA (ethylenediaminetetraacetic acid) tubes were used after prescreening confirmed that they had no contamination. The lot number and expiration dates for all vacuum sample vials, needles, and reagents were recorded.

Specific QC procedures were followed in the laboratory as well. For example, the freezers, refrigerators, and centrifuges were cleaned before the MEC opened, and a temperature reading on these items was conducted daily. On-site calibrations were performed twice each year. The NCHS biomedical engineer certified the revolutions per minute (rpm) of the centrifuges periodically and replaced the high-efficiency particulate air (HEPA) filters as necessary. All instrument maintenance was recorded. NHANES laboratories participated in the College of American Pathologists (CAP) proficiency-testing program. CAP samples were sent three times a year for the CBC and qualitative serum human chorionic gonadotropin (hCG). In addition, blind split samples were used for QC determinations.

Contract laboratories followed QA/QC guidelines when working with NHANES specimens, and were required to be CLIA-certified. In addition, to ensure the data quality, NHANES staff conducted annual laboratory inspections and reviewed the QC data from each laboratory.

Data Preparation

Routine data preparation procedures included a review of frequency data, outliers, and technician notes. Analysts should review the data reported for each component or laboratory assay, prior to beginning data analyses. Analysts should examine the data distribution and consider whether or not it is appropriate to include or exclude extreme values in a given analysis.

Low Detection Limits

For laboratory tests with a lower detection limit, results below the lower detection limit were replaced with a value equal to the detection limit, divided by the square root of two. This value was created to help users distinguish a nondetectable laboratory test result from a measured laboratory test result.

Laboratory Subsamples

Some NHANES components were collected or processed on a subset sample (subsample) of individuals. Subsampling was done to reduce participant burden and facilitate the scheduling and completion of examinations. Each subsample was selected to be a nationally representative sample. For example, some participants were selected to give a fasting blood sample on the morning of their examination. The subsamples selected for these components were chosen at random with a specified sampling fraction (e.g., one-half of the total examined group), according to the protocol for that component. Each component subsample has its own designated weight, which accounts for the additional probability of selection into the subsample component, as well as any additional nonresponse to the component. For some components, subsample weights were calculated to incorporate additional information relevant to data collection (such as day of the week for the dietary recall data). See the respective survey protocol and documentation for more specific information on each subsample.

Please note that when merging full sample data items to the subsample data files, the analytic sample is the subsample and the subsample weights must be used. Users are strongly urged to read the data file documentation and to take great care to ensure proper analysis and interpretation of the data.

Please refer to the NHANES Analytic Guidelines and the Continuous NHANES Web Tutorials for further details on NHANES subsamples, the use of sample weights, and other related analytic issues.

Special Analytic Notes for the Laboratory Data

The analysis of NHANES 2015-2016 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 weight variables. The Fasting Questionnaire File includes auxiliary information, such as fasting status, the time of venipuncture, and the conditions precluding venipuncture. The demographics and fasting questionnaire files may be linked to the laboratory data file using the unique survey participant identifier (i.e., SEQN).

In addition, we strongly encourage that all data users, prior to any analysis of the data, read all relevant documentations on the survey overall and for the specific data files to be used in their analysis. Specific data file documentation can be found via the link next to the respective data file on the NHANES website. Data users should also reference the NHANES Analytic Guidelines prior to beginning any analyses.

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