National Health and Nutrition Examination Survey

2015-2016 Data Documentation, Codebook, and Frequencies

Apolipoprotein B (APOB_I)

Data File: APOB_I.xpt

First Published: January 2019

Last Revised: NA

Note: See Analytic Note on Regression equations to compare 2015-2016 and 2013-2014 Apolipoprotein B data

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Component Description

The goals of this component are: 1) to monitor the prevalence and trends in major cardiovascular conditions, and overall risk factors in the U.S.; and 2) to evaluate prevention and treatment programs targeting cardiovascular disease in the United States.

Blood lipid levels are the main elements of the cardiovascular disease laboratory component in NHANES. Cardiovascular disease is the leading cause of death in the United States. The data will be used to monitor the status of hyperlipidemia, and the success of the National Cholesterol Education Program.

Eligible Sample

Participants aged 12 years and older, who were examined in the morning session, were eligible.

Description of Laboratory Methodology

In an immunochemical reaction, apolipoprotein B (Apo B) in a human serum sample will form immune complexes with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of Apo B in the sample. The result is evaluated by comparison with a standard of known concentration.

Apo B is the main protein component of LDL and accounts for approximately 95% of the total protein content of LDL. Apo B is necessary for the reaction with LDL receptors in the liver and on cell walls, and is thus involved in transporting cholesterol from the liver to the vessel cell. Elevated levels of Apo B are frequently found in patients with atherosclerotic vascular changes and are a risk factor for atherosclerosis.

Refer to the Laboratory Method Files section for a detailed description of the laboratory

methods used.

There were no changes to the lab method, or lab site for this component in the NHANES 2015-2016 cycle. However there was a change in lab equipment. In the 2013-2014 cycle, Apo B was measured on the Siemens Prospec chemistry analyzer. In the 2015-2016 cycle, Apo B was measured on the Roche Cobas 6000 chemistry analyzers. Please see Analytic Notes section for additional information comparing data between the 2013-2014 and 2015-2016 survey cycles.

Laboratory Method Files

Apolipoprotein B (January 2019)

Laboratory Quality Assurance and Monitoring

Serum specimens were processed, stored, and shipped to University of Minnesota, Minneapolis, MN for analysis.

Detailed instructions on specimen collection and processing are discussed in the NHANES Laboratory Procedures Manual (LPM). Vials are stored under appropriate frozen (–30°C) conditions until they are shipped to University of Minnesota for testing.

The NHANES quality assurance and quality control (QA/QC) protocols meet the 1988 Clinical Laboratory Improvement Act mandates. 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.

NCHS developed and distributed a quality control protocol for all CDC and contract laboratories, which outlined the use of Westgard rules (Westgard et al, 1981) when running NHANES 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.

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

Subsample Weights

Apo B was measured in a fasting subsample of participants 12 years and older. Special sample weights are required to analyze these data properly. Specific sample weights for this subsample are included in this data file and should be used when analyzing these data.

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.

The Fasting Questionnaire File includes auxiliary information such as fasting status, length of fast and the time of venipuncture.

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

Detection Limits

The detection limits were constant for all of the analytes in the data set. The variable prefixed LBX (ex., LBXAPB) provides the analytic result for that analyte.

The lower limit of detection (LLOD in mg/dL) for Apolipoprotein (B):

Variable Name	SAS Label	LLOD
LBXAPB	Apolipoprotein (B) (mg/dL)	25.0

Apo B regression equations to compare 2015-16 and 2013-14 data:

A method validation (bridging) study was performed to compare results from an instrument and method change in 2015-2016 cycle using NHANES samples from late 2014. The Roche Cobas 6000 Chemistry Analyzer (turbidimetric immunoassay) was used for all of the 2015-2016 cycle, while the Siemens ProSpec Analyzer (nephelometric immunoassay) was used in the 2013-2014 cycle. Randomly selected serum samples (n=105) from NHANES participants in 2014 were measured using both instruments, and the results were used to conduct the analysis. On average, apolipoprotein B values measured from the Roche Cobas 6000 Chemistry Analyzer (new instrument and turbidimetric method) were 3.7% higher than values from the Siemens ProSpec Analyzer (old instrument and nephelometric method) ($p<.0001$), and the correlation coefficient (r) between the measurements was 0.988. Regression analyses were performed using Analyse-it, v4.30.4. Given that the data showed proportional differences in variability, a weighted Deming regression was chosen to adjust the serum Apo B results (mg/dL). The forward and backward equations are below:

Forward: **Y** *(Cobas 6000)* **= 1.001** (95%CI: 0.9798 to 1.023) *** X** *(Siemens ProSpec)* **+ 2.883** (95%CI: 1.217 to 4.550)

Backward: **Y** *(Siemens ProSpec)* **= 0.9988** (95%CI: 0.9774 to 1.020) *** X** *(Cobas 6000)* **- 2.880** (95%CI: -4.601 to -1.158)

These regression equations should be used when examining trends of serum apolipoprotein B data across 2015-2016 and 2007-2014 cycles, or when combining 2015-2016 data with these previous cycles. For analysis involving apolipoprotein data from NHANES 2015-2016 and 2005-2006 cycles, please refer to the documentation accompanying 2005-2006 Apo B data (APOB_D) for additional adjustments, as a different instrument and laboratory were used to analyze 2005-2006 data.

References

- Westgard J.O., Barry P.L., Hunt M.R., Groth T. A multi-rule Shewhart chart for quality control in clinical chemistry. Clin Chem (1981) 27:493-501.

Codebook and Frequencies

SEQN - Respondent sequence number

Variable Name:	SEQN
SAS Label:	Respondent sequence number
English Text:	Respondent sequence number
Target:	Both males and females 12 YEARS - 150 YEARS

WTSAF2YR - Fasting Subsample 2 Year MEC Weight

Variable Name: WTSAF2YR

SAS Label: Fasting Subsample 2 Year MEC Weight

English Text: Fasting Subsample 2 Year MEC Weight

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
13612.331812 to 521632.18583	Range of Values	2743	2743	
0	No Lab Result	448	3191	
.	Missing	0	3191	

LBXAPB - Apolipoprotein (B) (mg/dL)

Variable Name: LBXAPB

SAS Label: Apolipoprotein (B) (mg/dL)

English Text: Apolipoprotein (B) (mg/dL)

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
22 to 211	Range of Values	2722	2722	
.	Missing	469	3191	

LBDAPBSI - Apolipoprotein (B) (g/L)

Variable Name: LBDAPBSI

SAS Label: Apolipoprotein (B) (g/L)

English Text: Apolipoprotein (B) (g/L)

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
0.22 to 2.11	Range of Values	2722	2722	
.	Missing	469	3191