National Health and Nutrition Examination Survey

2015-2016 Data Documentation, Codebook, and Frequencies

Ferritin (FERTIN_I)

Data File: FERTIN_I.xpt

First Published: May 2019

Last Revised: NA

Note: See Analytic Note describing the change in instrumentation in the 2015-2016 survey cycle.

Component Description

The objectives of this component are: 1) to provide data for monitoring secular trends in measures of nutritional status in the U.S. population; 2) to evaluate the effects of people's habits and behaviors, such as physical activity and the use of alcohol, tobacco, and dietary supplements on nutritional status; and 3) to evaluate the effect of changes in nutrition and public health policies, including welfare reform legislation, food fortification policy, and child nutrition programs, on the nutritional status of the U.S. population. These data will be used to estimate deficiencies and toxicities of specific nutrients in the population and subgroups, to provide population reference data, and to estimate the contribution of diet, supplements, and other factors to serum levels of nutrients. Data will be used for research to further define nutrient requirements, as well as optimal levels for disease prevention and health promotion.

Eligible Sample

Examined participants aged 1 to 5 years were eligible, and female participants aged 12 to 49 years were eligible.

Description of Laboratory Methodology

The method for measurement of Ferritin on the Roche Elecsys-170 is a sandwich principle with a total duration time of 18 minutes. The 1st incubation uses 10 uL of sample, a ferritin-specific antibody and a labeled ferritin-specific antibody to form a sandwich complex. The 2nd incubation occurs after the addition of microparticles that cause the complex to bind to the solid phase. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed. Application of a voltage to the electrode then induces chemiluminescent emission, which is measured by a photomultiplier. Results are determined via a calibration curve.

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 were changes to the lab equipment. In 2016, the laboratory instrumentation changed from the Roche Elecsys-170 to the Roche e601 instrument.

Laboratory Method Files

Ferritin Laboratory Procedure Manual (May 2019)

Laboratory Quality Assurance and Monitoring

Serum samples were processed, stored, and shipped to the Division of Laboratory Sciences, National Center for Environmental Health, and 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). Vials were stored under appropriate frozen (−30°C) conditions until they are shipped to National Center for Environmental Health 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 during "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.

All QC procedures recommended by the manufacturers were followed. Reported results for all assays meet the Division of Laboratory Sciences' quality control and quality assurance performance criteria for accuracy and precision, similar to the Westgard rules (Caudill, et al. 2008).

Data Processing and Editing

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

One calculated variable (LBDFERSI) was created in this data file, using the formula as follows:

LBDFERSI: The ferritin measurement in ng/mL (LBXFER) was converted to µg/L (LBDFERSI) by multiplying LBXFER by 1.0 (rounded to 3 significant figures).

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 other analytic issues.

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. Two variables are provided for each of these analytes. The variable name ending "LC" (ex., LBDFERLC) indicates whether the result was below the limit of detection: the value "0" means that the result was at or above the limit of detection, "1" indicates that the result was below the limit of detection. The other variable prefixed LBX (ex., LBXFER) provides the analytic result for that analyte. For analytes with analytic

results below the lower limit of detection (ex., LBDFERLC=1), an imputed fill value was placed in the analyte results field. This value is the lower limit of detection divided by the square root of 2 (LLOD/sqrt[2]).

The lower limit of detection (LLOD in ng/mL) for LBXFER:

Variable Name	SAS Label	LLOD
LBXFER	Ferritin	0.500 ng/mL

Ferritin regression equations to compare 2015-16 and 1999-2010 data:

A method validation (bridging) study was performed to compare results from an instrument change in the 2015-2016 cycle with earlier data.

The Roche Mod E170 analyzer was used for most of 2015-2016 and replaced with the Roche Cobas e601 analyzer in mid-2016. Randomly selected serum samples (n=188) from NHANES 2015-2016 participants, QC material, and proficiency testing specimens were measured using both instruments and the results were used to conduct the analysis. On average, ferritin values measured from the Roche e601 analyzer were 8.8% higher than values from the Roche Mod E170 (p<.0001). Data from the bridging study indicated the correlation coefficient (*r*) between the measurements was 0.999. 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 ferritin results (ng/mL).The forward and backward equations are below:

Forward: **Y** *(e601)* = **0.2243** (95%CI: -0.0069 – 0.4554) **+ X** *(E170)* *** 1.079** (95%CI: 1.070 – 1.088)

Backward: **Y** *(E170)* = **-0.2079** (95%CI: -0.4233 – 0.0074) **+ X** *(e601)* *** 0.9271** (95%CI: 0.9195 – 0.9348)

These regression equations should be used when examining trends of plasma glucose data across 2015-2016 and 2009-2010 cycles, or combining 2015-2016 data with these previous cycles. For analysis involving 2015-2016 data and data collected prior to 2009-2010 cycle, please refer to the documentation accompanying the 2009 -2010 (FERTIN_F) and 2003-2004 (L06TFR_C) ferritin data for additional adjustments.

Results in this 2015-2016 dataset from specimens analyzed using the Roche MOD E170 were adjusted using the above forward regression equation.

References

- Caudill, S.P., Schleicher, R.L., Pirkle, J.L. Multi-rule quality control for the age-related eye disease study. Statist. Med. (2008) 27(20):4094-40106.
- 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 1 YEARS - 5 YEARS
Target:	Females only 12 YEARS - 49 YEARS

LBXFER - Ferritin (ng/mL)

Variable Name: LBXFER

SAS Label: Ferritin (ng/mL)

English Text: Ferritin (ng/mL)

Target: Both males and females 1 YEARS - 5 YEARS

Target: Females only 12 YEARS - 49 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1.84 to 2300	Range of Values	2684	2684	
.	Missing	568	3252	

LBDFERSI - Ferritin (ug/L)

Variable Name:	LBDFERSI
SAS Label:	Ferritin (ug/L)
English Text:	Ferritin (ug/L)
Target:	Both males and females 1 YEARS - 5 YEARS
Target:	Females only 12 YEARS - 49 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1.84 to 2300	Range of Values	2684	2684	
.	Missing	568	3252	