National Health and Nutrition Examination Survey

2015-2016 Data Documentation, Codebook, and Frequencies

Insulin (INS_I)

Data File: INS_I.xpt

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Last Revised: NA

Component Description

Diabetes is a leading cause of disease and death in the United States. More than 29 million Americans are living with diabetes, and 86 million are living with prediabetes, a serious health condition that increases a person's risk of type 2 diabetes and other chronic diseases. In 2014, nearly 9.3 percent of all deaths for persons over the age of 25 were among people with diabetes. The prevalence of diabetes and overweight (one of the major risk factors for diabetes) continue to increase. Substantial new efforts to prevent or control diabetes have begun, including the Diabetes Prevention Trial and the National Diabetes Education Program.

Eligible Sample

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

Description of Laboratory Methodology

Insulin is the primary hormone responsible for controlling glucose metabolism, and its secretion is determined by plasma glucose concentration. The insulin molecule is synthesized in the pancreas as pro-insulin and is later cleaved to form C-peptide and insulin. The principal function of insulin is to control the uptake and utilization of glucose in the peripheral tissues. Insulin concentrations are severely reduced in insulin-dependent diabetes mellitus (IDDM) and some other conditions, while insulin concentrations are raised in non-insulin-dependent diabetes mellitus (NIDDM), obesity, and some endocrine disorders.

The Elecsys 2010 Insulin chemiluminescent "sandwich" immunoassay employs two monoclonal antibodies; which together are specific for human insulin. During the first incubation, a 20 μ L serum sample, a biotinylated monoclonal insulin-specific antibody, and a monoclonal insulin-specific antibody labeled with a ruthenium complex (Tris [2, 2'-

bipyridyl]ruthenium(II)-complex (Ru(bpy)) form a sandwich complex. During the second incubation, after the addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.

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 with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission, which is measured by a photomultiplier. The amount of light produced is directly proportional to the amount of insulin in the sample.

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

There were no changes to the lab method, lab equipment, or lab site for this component in the NHANES 2015-2016 cycle.

Laboratory Method Files

Insulin (June 2018)

Laboratory Quality Assurance and Monitoring

Serum samples are processed, stored, and shipped to the University of Missouri-Columbia, Columbia, MO 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 the University of Missouri – Columbia 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.

One variable was created in this data file using the following formula:

LBXIN and LBDINSI:

The insulin value in μ U/mL (LBXIN) was converted to pmol/L (LBDINSI) by multiplying by 6.0 (rounded to 2 decimals).

Analytic Notes

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

Subsample Weights

Insulin were measured in a fasting subsample of persons 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, the 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 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., LBDINLC) 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. For analytes with analytic results below the lower limit of detection (ex., LBDINLC=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 other variable prefixed LBX (ex., LBXIN) provides the analytic result for that analyte.

The lower limit of detection (LLOD, in uU/mL) for insulin is:

Variable Name	SAS Label	LLOD
LBXIN	Insulin	1.0

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

• 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 I tem
13612.331812 to 521632.18583	Range of Values	2743	2743	
0	No Lab Result	448	3191	
	Missing	0	3191	

LBXIN - Insulin (uU/mL)

Variable Name: LBXIN

SAS Label: Insulin (uU/mL)

English Text: Insulin (uU/mL)

Target: Both males and females 12 YEARS - 150 YEARS

Hard Edits: 0 to 9999.99

Code or Value	Value Description	Count	Cumulative	Skip to I tem
0.71 to 324.06	Range of Values	2921	2921	
	Missing	270	3191	

LBDINSI - Insulin (pmol/L)

Variable Name: LBDINSI

SAS Label: Insulin (pmol/L)

English Text: Insulin (pmol/L)

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	V	alue Description	Count	Cumulative	Skip to I tem
4.26 to 1944.36	Rang	ge of Values	2921	2921	
	Miss	ing	270	3191	

LBDINLC - Insulin Comment Code

Variable Name: LBDINLC

SAS Label: Insulin Comment Code

English Text: Insulin Comment Code

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Desc	ription	Count	Cumulative	Skip to I tem
0	0		2920	2920	
1	1	\	1	2921	
	Missing		270	3191	

PHAFSTHR - Total length of 'food fast', hours

Variable Name: PHAFSTHR

SAS Label: Total length of 'food fast', hours

English Text: Total length of 'food fast', hours

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to I tem
0 to 37	Range of Values	3135	3135	
	Missing	56	3191	

PHAFSTMN - Total length of 'food fast', minutes

Variable Name: PHAFSTMN

SAS Label: Total length of 'food fast', minutes

English Text: Total length of 'food fast', minutes

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Co	ount	Cumulative	Skip to I tem
0 to 59	Range of Values	313	35	3135	
	Missing	56	\	3191	