Do not use this file

National Health and Nutrition Examination Survey

2015-2016 Data Documentation, Codebook, and Frequencies

Hepatitis C: RNA (HCV-RNA) and Hepatitis C Genotype (HEPC_I)

Data File: HEPC_I.xpt

First Published: September 2017

Last Revised: September 2017

Note: The confirmatory test for the Hepatitis C screening test was discontinued by the manufacturer in 2012. A new confirmatory test (HCV INNO_LIA) to confirm Hepatitis C antibody (Anti-HCV) was implemented/validated and will be released in the RDC (SSHEPC_I).

Component Description

Hepatitis viruses constitute a major public health problem because of the morbidity and mortality associated with the acute and chronic consequences of these infections. New immunization strategies have been developed to eliminate the spread of hepatitis B virus (HBV) and hepatitis A virus (HAV) in the United States. Recommendations have also been developed for the prevention and control of hepatitis C virus (HCV) infection. Because of the high rate of asymptomatic infection with these viruses, information about the prevalence of these diseases is needed to monitor prevention efforts. By testing a nationally representative sample of the U.S. population, NHANES will provide the most reliable estimates of age-specific prevalence needed to evaluate the effectiveness of the strategies to prevent these infections. In addition, NHANES provides the means to better define the epidemiology of other hepatitis viruses. NHANES testing for markers of infection with hepatitis viruses will be used to determine secular trends in infection rates across most age and racial/ethnic groups, and will provide a national picture of the epidemiologic determinants of these infections.

In 2013, CDC revised its guidelines for Hepatitis C (HCV) testing because of 1) changes in the availability of certain commercial HCV antibody tests; 2) evidence that many persons who are identified as reactive by an HCV antibody test might not subsequently be evaluated to determine if they have current HCV infection; and 3) there have been significant advances in the development of antiviral agents with improved efficacy against HCV.[1] This new guidance was adopted in the NHANES 2013-2014 cycle, and is reflected in the following datasets:

2013-2014: SSHEPC_H (HCV confirmatory antibody – INNO-LIA) and HEPC_H (HCV RNA & Genotype)

2015-2016: SSHC_I_R (2015 HCV confirmatory antibody – INNO-LIA), HEPC_I_R (2016 HCV confirmatory antibody – INNO-LIA) and HEPC_I (HCV RNA & Genotype)

The flow chart for the new Hepatitis C algorithm can be found in the laboratory method file or by following the MMWR link below.

Beginning in the 2017-2018 cycle, the HCV confirmatory antibody test (INNO-LIA) will be released in the HEPC dataset with HCV RNA and Genotype data.

1. https://www.cdc.gov/mmwr/pdf/wk/mm62e0507a2.pdf

Eligible Sample

Examined participants aged 6 years and older were eligible.

Description of Laboratory Methodology

Hepatitis C RNA (HCV-RNA)

The COBAS AMPLICOR HCV MONITOR Test, version 2 0 (v2.0) is an in vitro nucleic acid amplification test for the quantitation of Hepatitis C Virus RNA in human serum or plasma on the COBAS AMPLICOR Analyzer.

Hepatitis C genotype

The VERSANT ® HCV Genotype 2.0 Assay (LiPA) is a line probe assay designed to identify Hepatitis C virus (HCV) genotypes 1 to 6 in human serum or EDTA plasma samples. Subtype information is available in the majority of cases.

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. However, the confirmatory test for the Hepatitis C screening test was discontinued by the manufacturer in 2012, and a new confirmed Hepatitis C antibody (Anti-HCV) will be retested by another confirmatory test (INNO-LIA HCV Score Test) and released at a later date in the RDC.

Laboratory Method Files

Hepatitis C Virus RNA (September 2017)

Hepatitis C Genotype (September 2017)

Laboratory Quality Assurance and Monitoring

Serum samples were processed, stored, and shipped to the Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, 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 are stored under appropriate frozen (–30°C) conditions until they are shipped to Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention 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.

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.

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.

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

Detection Limits

This data is qualitative. The use of lower limits of detection (LLODs) is not applicable.

Exam sample weights should be used for analyses. 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

- Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorian. Morbidity and Mortality Weekly Report. Centers for Disease Control and Prevention. May 7, 2013. <https://www.cdc.gov/mmwr/pdf/wk/mm62e0507a2.pdf>.

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 6 YEARS - 150 YEARS

LBXHCR - Hepatitis C RNA

Variable Name: LBXHCR

SAS Label: Hepatitis C RNA

English Text: Hepatitis C RNA

Target: Both males and females 6 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	50	50	
2	Negative	63	113	
3	Negative Screening HCV Antibody	6964	7077	
.	Missing	944	8021	

LBXHCG - Hepatitis C Genotype

Variable Name: LBXHCG

SAS Label: Hepatitis C Genotype

English Text: Hepatitis C Genotype

Target: Both males and females 6 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Genotype 1a	34	34	
2	Genotype 1b	6	40	
3	Gen1 other than a/b/not determined	0	40	
4	Genotype 2	5	45	
5	Genotype 3	4	49	
6	Genotype 4	0	49	
7	Genotype 5	0	49	
8	Genotype 6	0	49	
9	Genotype undetermined	1	50	
.	Missing	7971	8021	