National Health and Nutrition Examination Survey

2017-March 2020 Data Documentation, Codebook, and Frequencies

Hepatitis C: RNA (HCV-RNA), Confirmed Antibody (INNO-LIA), & Genotype (P_HEPC)

Data File: P_HEPC.xpt

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Component Description

The NHANES program suspended field operations in March 2020 due to the coronavirus disease 2019 (COVID-19) pandemic. As a result, data collection for the NHANES 2019-2020 cycle was not completed and the collected data are not nationally representative. Therefore, data collected from 2019 to March 2020 were combined with data from the NHANES 2017-2018 cycle to form a nationally representative sample of NHANES 2017-March 2020 pre-pandemic data. These data are available to the public. Please refer to the Analytic Notes section for more details on the use of the data.

Hepatitis viruses constitute a major public health problem because of the morbidity and mortality associated with the acute and chronic consequences of these infections. 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 provides 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 is used to determine secular trends in infection rates across most age and racial/ethnic groups and provide a national picture of the epidemiologic determinants of these infections (MMWR, 1998; MMWR, 2012).

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 (Moyer, 2013).

Eligible Sample

Examined participants aged 6 years and older in the NHANES 2017-March 2020 pre-pandemic sample 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 Confirmed Antibody (INNO-LIA)

In 2013, there was a change to the HCV testing algorithm. The flow chart for the HCV testing algorithm can

be found in the laboratory method file or by following the MMWR link: https://www.cdc.gov/mmwr/pdf/wk/mm62e0507a2.pdf.

Samples found reactive to the HCV antibody screening test are tested for HCV RNA. All HCV RNA positive samples were tested for HCV genotype, and only HCV RNA negative samples were tested with an HCV antibody confirmation test.

For the antibody confirmation test, the manual 16-hour sample incubation test procedure is used, where 10ul of specimens and controls are diluted in 1mL diluent in test troughs to ensure test strips will slide easily and remain submerged during incubation. Specimens and controls are incubated with agitation by rocker at 34 rpm overnight (16±2 hours) at room temperature (18–25°). After a 3X/5min each wash step on microtiter plate shaker, conjugate is added with a 30-minute incubation at room temperature, followed by aspiration, 3X/5min each wash step and 30-minute incubation in substrate solution also on microtiter plate shaker. Finally, strips are agitated with stop solution for 10–30 minutes at room temperature. The microtiter plate shaker is set for 160 rpm and used for all the washes and solution incubations. Strips are then dried completely in a dry incubator at 37°C for 30 minutes then mounted on the line immunoassay score data reporting sheet with inverted tape for reading within one hour using the reading card. The strips have lines for a background control, three reference lines for antibody (level ±, human IgG, weak positive; level 1+ human IgG, moderate positive; and level 3+, anti-human Ig, strong positive), and six lines for HCV antigens (C1, C2, E2, NS3, NS4, and NS5). Samples with a positive antibody confirmation test result are reported as positive. Samples with a negative antibody confirmation test result are reported as negative. Samples with an indeterminate antibody confirmation test result are released as missing. Only specimens insufficient in quantity are deemed indeterminate (WHO, 2015).

Hepatitis C genotype

HCV-RNA positive samples were then tested with a line probe assay to determine the HCV genotype.

The VERSANT ® HCV Genotype 2.0 Assay (LiPA) is a line probe assay designed to identify Hepatitis C virus (HCV) genotypes. Six genotypes (1-6), and three subtypes for genotype 1 (1a-b and 1-undertermined) can be identified in human serum or EDTA plasma samples. Genotype information is available in the majority of cases, including undetermined genotype. Genotype 1 is the most prevalent genotype in the U.S.

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

Laboratory Method Files

The method file will be available soon.

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 2017-2018 and 2019-2020 Laboratory Procedures Manuals (LPMs). Vials were stored under appropriate frozen (–30°C) conditions until they were 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 LPMs.

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 QC 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

The COVID-19 pandemic required suspension of NHANES 2019-2020 field operations in March 2020 after data were collected in 18 of the 30 survey locations in the 2019-2020 sample. Data collection was cancelled for the remaining 12 locations. Because the collected data from 18 locations were not nationally representative, these data were combined with data from the previous cycle (2017-2018) to create a 2017-March 2020 pre-pandemic data file. A special weighting process was applied to the 2017-March 2020 pre-pandemic data file. The resulting sample weights in the demographic data file should be used to calculate estimates from the combined cycles. These sample weights are not appropriate for independent analyses of the 2019-2020 data and will not yield nationally representative results for either the 2017-2018 data alone or the 2019-March 2020 data alone. Please refer to the NHANES website for additional information for the NHANES 2017-March 2020 pre-pandemic data, and for the previous 2017-2018 public use data file with specific weights for that 2-year cycle.

Refer to the 2017-2018 and 2019-2020 Laboratory Data Overview documents for general information on NHANES laboratory data.

There are over 800 laboratory tests performed on NHANES participants. However, not all participants provided biospecimens or enough volume for all the tests to be performed. The specimen availability can also vary by age or other population characteristics. For example, in the 2017-March 2020 approximately 76% of children aged 1-17 years who were examined in the MEC provided a blood specimen through phlebotomy, while 95% of examined adults aged 18 and older provided a blood specimen. Analysts should evaluate the extent of missing data in the dataset related to the outcome of interest as well as any predictor variables used in the analyses to determine whether additional re-weighting for item non-response is necessary.

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.

Demographic and Other Related Variables

The analysis of NHANES laboratory data must be conducted using the appropriate survey design and demographic variables. The NHANES 2017–March 2020 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

Exam sample weights should be used for analyses. This data is qualitative. The use of lower limits of detection (LLODs) is not applicable.

References

- Centers for Disease Control and Prevention. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. MMWR 1998;47(No. RR-19):1-39. Available from: https://www.cdc.gov/mmwr/PDF/RR/RR4719.pdf
- Centers for Disease Control and Prevention. Recommendations for the identification of chronic hepatitis C virus infection among persons born during 1945-1965. MMWR. 2012;61(RR-4):1-32. Available from: http://www.cdc.gov/mmwr/pdf/rr/rr6104.pdf
- Moyer VA. Screening for Hepatitis C Virus Infection in Adults: U.S. Preventive Services Task Force Recommendation Statement. Annals of Internal Medicine. 2013;159(5):349-357. Available from: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/hepatitis-c-screening
- World Health Organization. Prequalification of In Vitro Diagnostics Public Report: INNO-LIA HCV Score. PPQDx 0202-073-00. July 24, 2015. Available from: Public Report for INNO-LIA HCV Score, (PQDx 0202-073-00) | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

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	89	89	
2	Negative	168	257	
3	Negative Screening HCV Antibody	10550	10807	
.	Missing	1391	12198	

LBDHCI - Hepatitis C Antibody (confirmed)

Variable Name: LBDHCI

SAS Label: Hepatitis C Antibody (confirmed)

English Text: Hepatitis C Antibody (confirmed)

Target: Both males and females 6 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	98	98	
2	Negative	52	150	
3	Negative Screening HCV Antibody	10550	10700	
4	Positive HCV RNA	89	10789	
.	Missing	1409	12198	

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	49	49	
2	Genotype 1b	14	63	
3	Gen 1 other than a/b/not determined	1	64	
4	Genotype 2	9	73	
5	Genotype 3	10	83	
6	Genotype 4	1	84	
7	Genotype 5	0	84	
8	Genotype 6	1	85	
9	Genotype undetermined	2	87	
.	Missing	12111	12198	