National Health and Nutrition Examination Survey

2017-March 2020 Data Documentation, Codebook, and Frequencies

Hepatitis E: IgG & IgM Antibodies (P_HEPE)

Data File: P_HEPE.xpt

First Published: August 2022

Last Revised: NA

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. Infection with hepatitis E virus (HEV) has been responsible for large water-borne epidemics of acute disease in developing countries and for acute sporadic disease in industrialized developed countries. In immunocompromised individuals, infection with HEV may also cause chronic infection, which may progress to fibrosis and cirrhosis. 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 will provide a national picture of the epidemiologic determinants of these infections.

Eligible Sample

Examined participants aged 6 years or older in the NHANES 2017-March 2020 pre-pandemic sample were eligible.

Description of Laboratory Methodology

Hepatitis E IgG Antibody (IgG Anti-HEV)

The abia HEV IgG is an enzyme immunoassay kit intended for the detection of IgG antibodies to hepatitis E virus in human serum or plasma. During an initial incubation, HEV antibody in the sample binds with HEV antigen coated onto wells of a polystyrene stripped plate. Unbound sample is removed by washing. During a second incubation, horseradish peroxidase-labeled antibody conjugate (monoclonal mouse antibodies against human IgG) binds to any human IgG from the sample that was captured on the well. Unbound conjugate is removed by washing and a substrate solution containing tetramethylbenzidine is added to produce color. The reaction is stopped by adding a sulphuric acid solution and the optical density (OD) of each well is read. The presence or absence of IgG antibodies to hepatitis E virus is determined by the ratio of the OD of each sample to the calculated cut-off value. A sample is considered negative if the sample OD value is < cut-off and is considered positive if the sample OD value is ≥ cut-off.

Hepatitis E IgM Antibody (IgM Anti-HEV)

The abia HEV IgM is an enzyme immunoassay kit intended for the detection of IgM antibodies to hepatitis E virus in human serum or plasma. During an initial incubation, HEV antibody in the sample binds with HEV antigen coated onto wells of a polystyrene stripped plate. Unbound sample is removed by washing. During a second incubation, horseradish peroxidase-labeled antibody conjugate (monoclonal mouse antibodies against human IgM) binds to any human IgM from the sample that was captured on the well. Unbound conjugate is removed by washing and a substrate solution containing tetramethylbenzidine is added to produce color. The reaction is stopped by adding a sulphuric acid solution and the OD of each well is read. The presence or absence of IgM antibodies to hepatitis E virus is determined by the ratio of the OD of each sample to the calculated cut-off value. A sample is considered negative if the sample OD value is < cut-off and is considered positive if the sample OD value is ≥ cut-off.

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

Laboratory Method Files

Hepatitis E IgG Antibody (February 2020)

Hepatitis E IgM Antibody (February 2020)

Hepatitis E IgG Antibody (August 2022)

Hepatitis E IgM Antibody (August 2022)

Laboratory Quality Assurance and Monitoring

Serum specimens 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.

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

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

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

LBDHEG - Hepatitis E IgG (anti-HEV)

Variable Name: LBDHEG

SAS Label: Hepatitis E IgG (anti-HEV)

English Text: Hepatitis E IgG (anti-HEV)

Target: Both males and females 6 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	869	869	
2	Negative	10043	10912	
3	Indeterminate	0	10912	
.	Missing	1286	12198	

LBDHEM - Hepatitis E IgM (anti-HEV)

Variable Name: LBDHEM

SAS Label: Hepatitis E IgM (anti-HEV)

English Text: Hepatitis E IgM (anti-HEV)

Target: Both males and females 6 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	241	241	
2	Negative	10671	10912	
3	Indeterminate	0	10912	
.	Missing	1286	12198	