National Health and Nutrition Examination Survey

2017-March 2020 Data Documentation, Codebook, and Frequencies

Hepatitis B: Core antibody, Surface antigen, and Hepatitis D antibody (P_HEPBD)

Data File: P_HEPBD.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 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 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.

Hepatitis is inflammation of the liver most often caused by a virus. Viral hepatitis is a major public health problem of global importance because of the ongoing transmission of viruses that cause the disease and increased morbidity and mortality associated with the acute and chronic consequences of these infections. Global and US goals have been established for elimination of viral hepatitis as a public health threat by 2030 (HHS Healthy People, 2022 and HHS 2020).

In the US, the most common types of viral hepatitis are hepatitis A, B, and C. Effective vaccines are available to help prevent hepatitis A and hepatitis B. No vaccine is available for hepatitis C; however, highly effective, well-tolerated treatment can cure hepatitis C virus infection. Hepatitis D virus infection is less common in the US and can occur only among persons with hepatitis B virus infection. Hepatitis E infection also is less common in the US. These five hepatitis viruses, also called hepatitides, are well-characterized for detection with laboratory assays and are monitored in U.S. public health surveillance systems.

NHANES viral hepatitis data are used to monitor progress toward goals in *Healthy People* and the HHS *Viral Hepatitis National Strategic Plan*, which in turn support US and global viral hepatitis elimination goals (HHS Healthy People, 2022 and NASEC, 2017). The viral hepatitis laboratory and interview components of NHANES complement data from outbreak, case-based surveillance, vital statistics, health care systems, and cohort studies that can provide timely, detailed, or longitudinal information for subnational geographic areas and disproportionately affected populations, such as persons experiencing homelessness or living in correctional facilities; however, these sources lack information available from NHANES, such as race, ethnicity, education, income, and health status and behaviors.

Viral hepatitis data from NHANES are available beginning with the Second NHANES conducted during 1976-1980 for hepatitis A and hepatitis B, and with the Third NHANES conducted during 1988-1994 for

hepatitis C, hepatitis D and hepatitis E.

An estimated 300 million people worldwide are persistent carriers of hepatitis B virus (HBV). Infection with HBV results in a wide spectrum of acute and chronic liver diseases that may lead to cirrhosis and hepatocellular carcinoma. Co-infection with hepatitis D virus (HDV) in persons with acute or chronic hepatitis B virus (HBV) infection can lead to fulminant hepatitis.

Transmission of HBV occurs by percutaneous exposure to blood products and contaminated instruments, sexual contact and perinatally from HBV-infected mothers to their unborn child.

HBV infection produces an array of unique antigens and antibody responses that, in general, follow distinct serological patterns.

Hepatitis B surface antigen (HBsAg), derived from the viral envelope, is the first antigen to appear following infection and can be detected serologically as an aid in the laboratory diagnosis of acute HBV infection.

Hepatitis B core antibody (anti-HBc) is detectable shortly after the appearance of hepatitis B surface antigen (HBsAg). As the appearance of anti-HBsAg may be delayed after HBsAg clearance, anti-HBc is sometimes the only serological marker for HBV infection and potentially infectious blood. Anti-HBc is found in acute and chronic hepatitis B patients and also indicates past resolved infection.

The Delta antigen/antibody system (HDAg/Anti-HDV) is related to HBV infection but immunologically distinct from its known reactivities; it is the expression of the Delta virus (Hepatitis D Virus, HDV), a cause of severe liver disease in HBsAg carriers. HDV is a 35-37nm particle containing low molecular weight RNA and HDAg, with an outer coat of HBsAg obtained from HBV. HDV is a defective virus and its replication requires helper functions provided by HBV. HDAg has been detected in liver and in serum and induces a specific antibody response (anti-HDV antibodies) in both the IgG and IgM classes.

Tests for anti-HBc, HBsAg, and anti-HDV are conducted as part of the NHANES viral hepatitis component.

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 B core antibody (anti-HBc)

Hepatitis B core antibody is measured using the VITROS Anti-HBc assay, which is performed using the VITROS Anti-HBc Reagent Pack and VITROS Immunodiagnostic Products Anti-HBc Calibrator on the VITROS ECi/ECiQ or VITROS 3600 Immunodiagnostic System.

The hepatitis B core antibody test is performed on all examined participants aged 6 years and older while the hepatitis B surface antibody test is performed on all examined participants aged 2 years old and older (reported in P_HEPB_S).

Hepatitis B surface antigen (HBsAg)

Hepatitis B surface antigen is measured using the VITROS HBsAg test, which is performed using the VITROS HBsAg Reagent Pack and VITROS Immunodiagnostic Products HBsAg Calibrator on the VITROS ECi/ECiQ Immunodiagnostic Systems and the VITROS 3600 Immunodiagnostic System.

The Hepatitis B surface antigen is tested only when the Hepatitis B core antibody test is positive or indeterminate.

Hepatitis D antibody (anti-HDV)

Hepatitis D antibody was measured using the DiaSorin ETI-AB-DELTAK-2 assay during 2017-2018 and the Anti-HDV IgG WES Assay during January 2019 through March 2020.

The Hepatitis Delta Virus (HDV) is a RNA defective virus; and an infection with HDV only occurs in the presence of acute or chronic HBV infection. In NHANES, the test for antibody to HDV is performed on all examined participants 6 years and older who test positive or indeterminate for anti-HBc and HBsAg.

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

Laboratory Method Files

Hepatitis B Core Antibody (February 2020)

Hepatitis B Surface Antigen (February 2020)

Hepatitis D Antibody (February 2020)

Hepatitis D Antibody (August 2022)

Hepatitis B Surface Antigen (August 2022)

Hepatitis B Core Antibody (August 2022)

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 2017-2018 and 2019-2020 NHANES 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 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 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 2020Demographics 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.

Hepatitis D Antibody (Delta) Method Change

The method for Hepatitis D Antibody (delta) changed between survey cycles 2017-2018 and 2019-2020. The commercial kit (Diasorin) used during the 2017-2018 survey cycle was discontinued by the manufacturer. The Diasorin test had a sensitivity of 100% (86.7-100) and a specificity of 100% (91.9-100), however, these sensitivity and specificity were not independently verified due to a lack of well characterized sample evaluation panel. A CDC laboratory developed test was used in 2019-2020 survey cycle and had a sensitivity of 96% and a specificity of 97%. The sensitivity and specificity for this newly developed method are verified using a convenience sample of NHANES specimens and non-NHANES specimens tested previously using the commercially available kit.

References

- National Academies of Sciences, Engineering, and Medicine. 2017. A national strategy for the elimination of hepatitis B and C. Washington, DC: The National Academies Press. Available from: http://www.nationalacademies.org/hmd/reports/2017/national-strategy-for-the-elimination-of-hepatitis-b-and-c.aspx
- U.S. Department of Health and Human Services. 2020. Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination (2021–2025). Washington, DC. Available from: https://www.hhs.gov/hepatitis/viral-hepatitis-national-strategic-plan/index.html
- U.S. Department of Health and Human Services. Healthy People. 2022. Available from: https://health.gov/our-work/national-health-initiatives/healthy-people

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

LBXHBC - Hepatitis B core antibody

Variable Name: LBXHBC

SAS Label: Hepatitis B core antibody

English Text: Hepatitis B core antibody

Target: Both males and females 6 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	641	641	
2	Negative	10275	10916	
3	Indeterminate	1	10917	
.	Missing	1281	12198	

LBDHBG - Hepatitis B surface antigen

Variable Name: LBDHBG

SAS Label: Hepatitis B surface antigen

English Text: Hepatitis B surface antigen

Target: Both males and females 6 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	45	45	
2	Negative	595	640	
3	Indeterminate	0	640	
.	Missing	11558	12198	

LBDHD - Hepatitis D antibody (anti-HDV)

Variable Name: LBDHD

SAS Label: Hepatitis D antibody (anti-HDV)

English Text: Hepatitis D antibody (anti-HDV)

Target: Both males and females 6 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Positive	6	6	
2	Negative	633	639	
3	Indeterminate	0	639	
.	Missing	11559	12198	