National Health and Nutrition Examination Survey

2017-March 2020 Data Documentation, Codebook, and Frequencies

Liver Ultrasound Transient Elastography (P_LUX)

Data File: P_LUX.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.

Chronic liver disease and cirrhosis are significant contributors to morbidity and mortality in the U.S. population. (Singh et al., 2013; Tapper and Parikh, 2018; Yoon, 2018). With the obesity epidemic, nonalcoholic fatty-liver disease is considered the most common cause of chronic liver disease in U.S. adults and children. Other important causes of chronic liver diseases in the general population include alcoholic liver disease and chronic viral hepatitis infections (C or B).

The main goals of the NHANES liver ultrasound transient elastography (variable name prefix LUX) component are to provide objective measures for two important liver disease manifestations: liver fibrosis (scarring in the liver) and hepatic steatosis (fat in the liver). A healthy liver is usually soft and flexible, but a person with liver disease tends to have a liver that is stiff. Liver fibrosis was measured by FibroScan® which uses ultrasound and the vibration controlled transient elastography (VCTE™) to derive liver stiffness. The device also simultaneously measures the ultrasound attenuation related to the presence of hepatic steatosis and records the controlled attenuation parameter (CAP™) as the indicator for the fatness in the liver. Elastography has been evaluated by others for its accuracy to assess liver steatosis and liver fibrosis (Tang et al, 2015, Castéra et al, 2005, Barr et al, 2015).

Eligible Sample

All participants 12 years and older in the NHANES 2017-March 2020 pre-pandemic sample were eligible. Participants were excluded if they (1) were unable to lie down on the exam table, (2) were pregnant (or unsure if pregnant) at the time of their exam, or a urine could not be obtained to test for pregnancy, (3) had an implanted electronic medical device, or (4) were wearing a bandage or had lesions on the right side of their abdomen by the ribs (where measurements would be taken).

Protocol and Procedure

A detailed description of the procedures was documented in the 2017-2018 and 2019-2020 Liver Ultrasound Transient Elastography Procedures Manuals of this component. The elastography measurements were obtained in the NHANES Mobile Examination Center (MEC), using the FibroScan® model 502 V2 Touch equipped with a medium (M) or extra-large (XL) wand (probe).

With FibroScan®, a mechanical vibration of mild amplitude and low frequency (50Hz) is transmitted through the intercostal space using a vibrating tip contacting the skin. The vibration induces a shear wave that

propagates through the liver. The displacements induced by the shear waves were tracked and measured using pulse echo ultrasound acquisition algorithms. The shear wave velocity is related directly to tissue stiffness; with harder tissues, there is faster shear wave propagation. Using the Young modulus, the velocity is converted into liver stiffness, and expressed in kilopascals. In systematic reviews comparing vibration controlled transient elastography (VCTE™) to biopsy (as a gold standard) for the detection of severe liver fibrosis, the mean area under the receiver operating characteristic (ROC) curve was 0.89 (95% CI, 0.88-0.91) (Tsochatzis et al, 2011, Friedrich-Rust et al, 2008) and the overall sensitivity and specificity were 82% (95% CI, 78-86%) and 86% (95% CI 0.80-0.91). In addition to the high accuracy, meta-analyses have demonstrated FibroScan® results carry significant prognostic value (Singh et al, 2013). Transient elastography has been FDA approved as a test for the evaluation of liver fibrosis.

The FibroScan® machine has also incorporated a novel physical parameter (controlled attenuation parameter or CAP™), which measures the ultrasound attenuation related to the presence of hepatic steatosis. The CAP measurement is recorded simultaneously with the liver stiffness measurement. The accuracy of the CAP measurement for the detection of steatosis against biopsy has been reported in few studies; for steatosis ≥10%, the area under the ROC curve is 0.81, with a sensitivity and specificity of 76% and 79%; for steatosis >34% these values were 0.80, 79% and 71%, respectively (Myers et al, 2012, de Ledinghen V et al, 2016, Sasso et al, 2016).

The elastography exam was performed by NHANES health technicians (HTs), who were trained and certified by NHANES staff and the equipment manufacturer (Echosens™ North America). The exams were performed according to the manufacturer guidelines. To help maintain a standardized data quality, the machine conducts and displays several quality control (QC) measures during the test: 1) the median of all valid measurements performed during the examination; 2) interquartile range (IQR) which represents the interval around the median within which 50% of all valid measurements will fall; and 3) IQR/M: the ratio of the IQR to the median stiffness. All these QC indexes were recalculated after each new measurement. HTs were trained to take 10 valid measurements with an IQR/M ratio less than 30%.

If the first 10 measurements taken had an IQR/M ≥ 30%, the HT may choose to capture additional measurements until the IQR/M index was lower than 30%. The HT also has the option to delete outlier measurements to lower the IQR/M from the list of valid measurements. It should be noted that HTs were only allowed to delete measurements from the beginning of the measurements. Once a measurement was chosen to be deleted, any measurements taken before the chosen one will be eliminated from the exam as well. This is to reduce bias, so HTs were unable to hand select which measurement(s) to delete.

The QC criteria of IQR/M <30% is to reduce variability and improve validity by taking measurements that result in few outliers. Multiple factors can affect the measurement and result in outliers, for example, a participant moves during the exam, or technical issues, such as the placement of the probe is not centered over the liver or perpendicular, or if structures such as lung or ribs appear while the measurement is captured. Participants with a lot of adipose tissue sometimes may make it difficult for HTs to capture 10 valid measurements. Because of the twelve-minute time limit and the challenge of locating the proper site to administer the exam on the body, HTs could end up retaining fewer than 10 valid measurements.

Quality Assurance & Quality Control

A detailed description of quality assurance and quality control measures considered for this component can be found in the 2017-2018 and 2019-2020 Procedures Manuals. Briefly, the NHANES HTs completed a 2-day training program with survey staff and an expert FibroScan® Technician (reference examiner). The training included an overview of the component, demonstrations conducted by the reference examiner with volunteer subjects. The reference examiner reviewed and demonstrated the proper technique of the FibroScan® examination. Supervised practice exercises followed, conducted with several volunteer subjects. The reference examiner would certify the HT after observing 3 satisfactory exams.

NHANES staff members and an external university-based medical epidemiologist with expertise in chronic liver disease, monitored MEC staff performance in the field through periodic visits and direct observations. HT performance was also monitored using data reviews for each health technician compared to all other HTs and annual reference examiner refresher training.

Multiple times per year NHANES staff, including the NHANES Senior Medical Officer, would select a sample of the original FibroScan® PDF files obtained by the HTs in the MEC for re-review. The samples selected for review include ones from new and experienced HTs, and participants with: 1) extreme stiffness (E), CAP, or E-IQR values, 2) stiffness (E) or CAP values that seemed unusual for younger participants, or 3) inconsistent extreme stiffness (E) and CAP values in the same person (i.e., low stiffness (E) and high CAP or high stiffness (E) and low CAP).

Annual FibroScan® wand calibration was performed by the manufacturer and software updates were performed according to manufacturer recommendations. In addition, NHANES used four shear wave liver fibrosis phantoms (CIRS Model 039) for determining variances within and between FibroScan® machines and probes over time.

Data Processing and Editing

Information obtained by staff in the MEC regarding pregnancy status/test results, fasting times, possible exam exclusions, and other comments were recorded in the NHANES database during the participant's MEC visit. All measures recorded by the FibroScan® machines were directly transferred via the Integrated Survey Information System to the NHANES database system immediately after each exam. HTs were instructed to visually verify that the values transferred correctly.

Computerized data quality control procedures were performed to check for completeness and data validity and to identify logical inconsistencies and extreme data values (e.g., fasting times lasting more than 40 hours) and rare deviations in the protocol (e.g., technical error for number of measures recorded or duplicate files due to exam restarts).

Prior to data release, NHANES staff reviewed extreme values and cross-checked with other available data for verification and reviewed free-text comments noted by MEC staff and made edits or corrections as appropriate.

The liver elastography exam status code (LUAXSTAT) was created and indicates the following for each participant:
1 = Complete exam (i.e., fasting time of at least 3 hours, 10 or more complete stiffness (E) measures, and a liver stiffness interquartile (IQRe) range / median E < 30%).
2 = Partial exam (i.e., either a fasting time < 3 hours, < 10 complete stiffness (E) measures, or a liver stiffness interquartile (IQRe) range / median E 30% or higher).
3 = Ineligible participant (see eligibility criteria above).
4= Not done (i.e., refusal, limited time during exam visit, other).

Reason codes for partial exams (LUARXNC), exams not done (LUARXND), and ineligible participants (LUARXIN) were created from MEC staff comments and included in this data release.

The number of measures attempted (LUANMTGP) and the number of measures recorded (LUANMVGP), using the final wand, were categorized at high end to 20 to 29, and 30 or more.

FibroScan® measures were not edited, and there are no imputed values in this file.

Elastography results were not reported to participants if they had <10 complete stiffness (E) measures or liver stiffness interquartile (IQRe) range/median E ≥ 30%, or fasted <3 hours, as recommended by the elastography equipment manufacturer. An exception to these criteria was permitted if the participant had an E value below the referral criteria and had at least 10 complete stiffness measures, even though the 3-hour fasting time was not satisfied. In this data file, elastography results are included for all participants regardless of the number of complete stiffness measures, the IQRe value, or the length of fast.

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 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.

As stated above no changes were made to the stiffness, controlled attenuation parameter, IQRe, or IQRc values obtained from the FibroScan® machine. Analysts should be aware that some extreme values may be present. Extreme values may be to the result of difficulty obtaining the measures due to participant body habitus (especially those who are obese or who have narrow intercostal spaces) or may represent truly high values.

Sample weights: the NHANES examination sample weights should be used to analyze elastography data unless it is merged with a more restrictive data file, such as the morning fasting sample, then use the sample weight appropriate for that more selective group.

Please refer to the NHANES Analytic Guidelines and the on-line NHANES Tutorials for further details on the use of sample weights and other analytic issues. Both are available on the NHANES website.

References

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- Yoon Y-HC, CM. Surveillance Report #111 Liver Cirrhosis Mortality in the United States: National, State and Regional Trends, 2000-2015. Arlington, VA; April2018.

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

LUAXSTAT - Elastography exam status

Variable Name: LUAXSTAT

SAS Label: Elastography exam status

English Text: Elastography exam status.

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Complete	9023	9023	LUAPNME
2	Partial	748	9771	
3	Ineligible	386	10157	LUARXIN
4	Not done	252	10409	LUARXND
.	Missing	0	10409	

LUARXNC - Reason for partial exam

Variable Name: LUARXNC

SAS Label: Reason for partial exam

English Text: Reason for partial exam.

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Fasting < 3hrs	371	371	LUAPNME
2	Unable to obtain 10 valid measures	179	550	LUAPNME
3	IQR/M >30%	198	748	LUAPNME
.	Missing	9661	10409	

LUARXND - Reason exam not done

Variable Name: LUARXND

SAS Label: Reason exam not done

English Text: Reason exam not done.

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Participant refusal	61	61	LUANMTGP
2	Limited time	76	137	LUANMTGP
3	Other (e.g. physical or technical limitations)	115	252	LUANMTGP
.	Missing	10157	10409	

LUARXIN - Reason ineligible

Variable Name: LUARXIN

SAS Label: Reason ineligible

English Text: Reason ineligible.

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1	Pregnant/ Unable to get urine to test for pregnancy	148	148	LUANMTGP
2	Other (e.g. insulin pump or other implantable electronic device)	238	386	LUANMTGP
.	Missing	10023	10409	

LUAPNME - Exam wand type

Variable Name: LUAPNME

SAS Label: Exam wand type

English Text: Exam wand type.

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
M	M	7265	7265	
XL	XL	2473	9738	
< blank >	Missing	671	10409	

LUANMVGP - Count:complete measures from final wand

Variable Name: LUANMVGP

SAS Label: Count:complete measures from final wand

English Text: Total number of complete measures retained (using final wand).

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
0	0	2	2	
1	1	12	14	
2	2	14	28	
3	3	14	42	
4	4	17	59	
5	5	12	71	
6	6	10	81	
7	7	16	97	
8	8	10	107	
9	9	19	126	
10	10	5727	5853	
11	11	1369	7222	
12	12	849	8071	
13	13	543	8614	
14	14	353	8967	
15	15	238	9205	
16	16	149	9354	
17	17	102	9456	
18	18	81	9537	
19	19	35	9572	
20	20 to 29	109	9681	
30	30 or more	21	9702	
.	Missing	707	10409	

LUANMTGP - Count:measures attempted with final wand

Variable Name: LUANMTGP

SAS Label: Count:measures attempted with final wand

English Text: Total number of measures attempted (using final wand).

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
0	Not done	671	671	End of Section
1	1	1	672	
3	3	1	673	
4	4	1	674	
5	5	2	676	
6	6	1	677	
9	9	2	679	
10	10	2727	3406	
11	11	1383	4789	
12	12	997	5786	
13	13	779	6565	
14	14	583	7148	
15	15	489	7637	
16	16	352	7989	
17	17	283	8272	
18	18	245	8517	
19	19	202	8719	
20	20 to 29	933	9652	
30	30 or more	757	10409	
.	Missing	0	10409	

LUXSMED - Median stiffness (E), kilopascals (kPa)

Variable Name: LUXSMED

SAS Label: Median stiffness (E), kilopascals (kPa)

English Text: Median liver stiffness (E). This indicator is presented with one digit to the right of the decimal ratio (e.g. XX.X), and the units for this measure are kilopascals (kPa).

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
1.6 to 75	Range of Values	9700	9700	
.	Missing	709	10409	

LUXSIQR - Stiffness E interquartile range (IQRe)

Variable Name: LUXSIQR

SAS Label: Stiffness E interquartile range (IQRe)

English Text: Stiffness (E) interquartile range (IQRe) of final stiffness measures. This indicator is presented with one digit to the right of the decimal (e.g., XX.X).

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
0 to 67.3	Range of Values	9706	9706	
.	Missing	703	10409	

LUXSIQRM - Ratio: Stiffness IQRe / median E

Variable Name: LUXSIQRM

SAS Label: Ratio: Stiffness IQRe / median E

English Text: Ratio of the stiffness IQRe / median E stiffness value. This indicator is presented as a percent with one digit to the right of the decimal (e.g., XX.X%).

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
0 to 1338	Range of Values	9691	9691	
.	Missing	718	10409	

LUXCAPM - Median CAP, decibels per meter (dB/m)

Variable Name: LUXCAPM

SAS Label: Median CAP, decibels per meter (dB/m)

English Text: Median controlled attenuated parameter (CAP). This indicator is presented as a whole number (e.g., XXX), and the units for this measure are decibels per meter (dB/m).

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
100 to 400	Range of Values	9698	9698	
.	Missing	711	10409	

LUXCPIQR - CAP interquartile range (IQRc)

Variable Name: LUXCPIQR

SAS Label: CAP interquartile range (IQRc)

English Text: Controlled attenuated parameter (CAP) interquartile range (IQRc) of final CAP measures. This indicator is presented as a whole number (e.g., XX).

Target: Both males and females 12 YEARS - 150 YEARS

Code or Value	Value Description	Count	Cumulative	Skip to Item
0 to 206	Range of Values	9689	9689	
.	Missing	720	10409	