

ICPSR 21600

National Longitudinal Study of Adolescent to Adult Health (Add Health), 1994-2018 [Public Use]

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Wave V: Biomarkers, Cardiovascular Measures User Guide

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Cardiovascular Measures

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Add Health is supported by grant P01-HD31921 from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, with cooperative funding from 23 other federal agencies and foundations.

This document summarizes the rationale, equipment, measurement, protocol and data cleaning procedures for each of the cardiovascular measures collected at the Wave V home exam. It also documents how constructed variables were derived from the cardiovascular measures collected in the field. Whenever possible, data collection and methods in Wave V mirrored those of Wave IV to ensure comparability of data between waves. This document is one in a set of Wave V user guides. User guides are also available to describe protocols for the following biological measures in Wave V:

- Anthropometrics
- Medication Use
- Baroreflex Sensitivity & Hemodynamic Recovery
- Glucose Homeostasis
- Inflammation and Immune Function
- Lipids
- Renal Function

Acknowledgement

This research uses data from Add Health, a program project directed by Kathleen Mullan Harris and designed by J. Richard Udry, Peter S. Bearman, and Kathleen Mullan Harris at the University of North Carolina at Chapel Hill, and funded by grant P01-HD31921 from the Eunice Kennedy Shriver National Institute of Child Health and Human Development, with cooperative funding from 23 other federal agencies and foundations. We gratefully acknowledge Carolyn Halpern, Nancy Dole, Joyce Tabor, and Sarah Dean for their dedication to the quality of the Add Health data in this document. Information on how to obtain the Add Health data files is available on the Add Health website (https://addhealth.cpc.unc.edu/).

Citation

Citations of this Add Health User Guide should use the following format: Whitsel, EA, Angel R, O'Hara R, Qu L, Carrier K, Harris K. Add Health Wave V Documentation: Cardiovascular Measures, 2020; Available from: https://doi.org/10.17615/gtme-ag52

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1. Introduction

The cardiovascular measures collected at Add Health Wave IV were also collected at the Wave V home exam in the following order:

- Arm Circumference (cm)
- Systolic blood pressure (SBP, mm Hg)
- Diastolic blood pressure (DBP, mm Hg)
- Pulse rate (PR, beats/min)

In addition, the Add Health Wave V cardiovascular data set includes nine constructed measures based on information collected at the home exam:

- Average systolic blood pressure
- Average diastolic blood pressure
- Average pulse rate
- Pulse pressure (mm Hg)
- Mean arterial pressure (mm Hg)
- Blood pressure classification based on JNC7
- Blood pressure classification based on AHA/ACC
- Antihypertensive medication use
- Joint classification of average blood pressures, history of health care provider-diagnosed high blood pressure, and antihypertensive medication use

2. General Overview of Data Collection

2.1. Biomarker Consent & Scheduled Home Exam

At the end of the Wave V Survey, respondents were asked if they would agree to participate in the Wave V home exam administered by a field examiner (FE), which included taking measurements and collecting a blood sample. If the participant agreed, examiners from the Add Health data collection partner (Section 2.2) scheduled a date and time for the home exam. Depending on participant and/or FE availability, the time between the Wave V Survey completion and the home exam ranged from days to years (see the time interval variable **H5TIMESE** in the *bdemo5* data set and codebook). Some respondents completed the home exam <u>before</u> completing the entire Wave V Survey, resulting in a negative time interval. There were two scenarios where this occurred:

a) Sample 1 respondents selected for administration of the modular questionnaire were asked to complete the biomarker consent section after completing Module A of the Web Questionnaire and Mail Questionnaire. These respondents could consent to and complete the home exam before continuing to complete Module B.¹ b) Respondents who completed the Sample 1 non-response follow up (NRFU) abbreviated telephone interview could consent to and complete the home exam before completing the full Wave V Survey.¹

2.2. Home Exam

All data were collected during home exams performed by FEs from two Add Health data collection partners: Examination Management Services, Inc. (2016-2017) and Hooper Holmes, Inc. (2018-2019). All FEs were trained and certified using a custom program specific to the Add Health protocol. FEs used a 7" Samsung Galaxy Tab 4 tablet to record and transmit data. An Add Health data collection application (Open Data Kit or ODK) installed on the tablet guided the FEs through the home exam protocol. In addition, FEs received a series of job aids, both on paper and on the tablet, to serve as quick reference guides when completing the protocol. Each tablet also contained an in-depth Add Health training manual that could be accessed at any time.

Once the home exam was initiated, a few preliminary questions were asked of respondents and then cardiovascular measures were collected. Respondents were free to skip any portion of the data collection or terminate the visit at any time. Particular care was taken to provide respondents with written documentation of mean blood pressures and current guideline-based recommendations for follow-up.

3. Arm Circumference (cm) [H5CIRCMF]

3.1 Rationale

Arm circumference was measured to guide selection of an appropriately sized blood pressure cuff for the cardiovascular measures.

3.2 Equipment

FEs used a SECA 201 metric-increment circumference soft tape measure (Seca Corp., North America East; Hanover, MD) to measure arm circumference (Exhibit 1).

Specifications:

- 200 cm maximum range
- 1 mm graduations
- 2-sided cm scaling
- 90 x 25 x 65 mm
- 50 g
- Fiberglass tape
- Plastic case
- Automatic roll-up
- End-peg positioned



Exhibit 1. SECA 201 tape measure

3.3 Measurement and Protocol

Trained and certified FEs measured right arm circumference and blood pressure unless one or more of the following contraindications was present:

- open sores, wounds, gauze dressings or rashes;
- casts, splints or shunts;
- intravenous (IV) catheters or other attached medical devices;
- swelling, withering or paralysis; or
- arm on same side as prior mastectomy.

If there were contraindications to the measurement of right arm circumference or blood pressure, FEs measured left arm circumference. If there were contraindications to measurement on both arms, arm circumference and blood pressure were not measured.

To measure arm circumference accurately, FEs asked respondents to remove bulky outer garments (e.g., sweaters or jackets) and, if applicable, push up their shirt sleeves to expose the upper arm. FEs also instructed respondents to relax their shoulders and allow their arm to be measured while hanging loosely at their side. FEs wrapped the SECA tape around the respondent's upper arm, midway between the shoulder and elbow. Arm circumference was measured to the nearest 0.5 cm and entered into the tablet which determined the appropriate cuff size for blood pressure measurement. Determination of cuff size and blood pressure measurement differed before and after the 2017-2018 transition between data collection partners (Exhibit 2):

Arm	2016-2017		2018-2019	
Circumference	BP	Cuff Size	ВР	Cuff Size
< 24.0 cm	Χ	Х	✓	Adult
24.0-29.9 cm	\checkmark	Adult	\checkmark	Adult
30.0-40.5 cm	\checkmark	Large Adult	\checkmark	Large Adult
> 40.5 cm	Χ	X	Χ	X

Exhibit 2. Cuff Size and Blood Pressure Measurement

3.4 Data Cleaning

Arm circumferences entered in inches were converted to centimeters. The skip logic and distribution of the entered arm circumferences were checked for outliers and inconsistencies. Outlying measured arm circumferences were identified using an extreme studentized deviate (ESD) multiple outlier detection procedure.² All outliers identified as described above were investigated for inconsistencies within Wave V. Clearly inconsistent Wave V arm circumferences were recoded to "invalid data" (H5ARMCIR=9999).

4. Cardiovascular Measures

4.1 Rationale

Blood pressure and pulse rate were measured because of their established relationship with cardiovascular disease morbidity and mortality.

4.2 Equipment

FEs used a factory calibrated, Microlife BP3MC1-PC-IB oscillometric blood pressure monitor (MicroLife USA, Inc.; Dunedin, FL) recommended for clinical and home use by the British Hypertension Society (Exhibit 3) and an Adult or Large Adult cuff to measure blood pressure and pulse rate. Specifications:

Weight: 735 g (with batteries)

• Size: 160 (W) x 140 (L) x 98 (H) mm

Storage Temperature: 20°C-50°C (-4°F -122°F)

Humidity: 15%-90% relative humidity maximum

Operation Temperature: 10°C-40°C (50°F-104°F)

Display: Liquid crystal display (LCD)

• Measuring Method: Oscillometric

Pressure Sensor: Capacitive

Measuring Range: 30-280 mmHg (SBP and DBP); 40 to 200 beats/min (PR)

Cuff Pressure Display Range: 0-299 mmHg

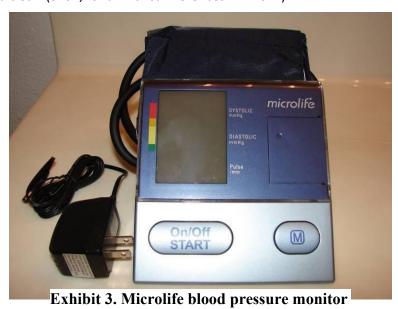
Measuring Resolution: 1 mmHg

Accuracy: ±3 mmHg (SBP & DBP); ±5 % (PR)

Power Source: [1] 4 AA batteries, 1.5V [2] AC Adapter 6V DC 600 mA (4.5-6 V DC)

• Adult Cuff (S101, for arm circumferences: 9.5-13.25 in)

• Large Adult Cuff (S102, for arm circumferences: 12-16 in)



4.3 Measurement

Trained and certified FEs measured resting, seated systolic and diastolic blood pressure (mmHg) and pulse rate (beats/minute). Three serial measurements were collected separated by at least 30-second intervals. Readings from the display on the BP monitor were keyed into the tablet ODK. Variable names were as listed in Exhibit 4.

Measure	Variable	Measure	Variable	Measure	Variable
SBP #1	Q031	DBP #1	Q032	PR #1	Q033
SBP #2	Q036	DBP #2	Q037	PR #2	Q038
SBP #3	Q041	DBP #3	Q042	PR #3	Q043

Exhibit 4. Variable Names of Direct Measures

4.4 Protocol

FEs used the Microlife blood pressure monitor supplied by Add Health unless unable to do so. When an alternate monitor was used, the reason was recorded in the tablet (occurred in 20 [0.4%] of the 5,381 exams).

Respondents who left their seat for any reason during the five minutes before blood pressure measurement were reseated. All respondents rested with both feet on the floor and legs uncrossed for five minutes before and during blood pressure measurement. FEs positioned the Microlife monitor display so that it was outside the view of respondents.

FEs collected three measurements of blood pressure and pulse rate separated by at least 30 second intervals. During each interval, respondents raised their elbow to the level of the shoulder and held the forearm upward at a 90-degree angle for five seconds after which the tablet presented a 20 second countdown ending in a visual cue and audible chime to prompt the next measurement. Immediately following each of the three measurements, FEs keyed the systolic and diastolic blood pressures and pulse rate into the tablet ODK.

In the event of a measurement error, FEs keyed the error message code from the Microlife display into the tablet ODK. The tablet returned the appropriate, i.e. manufacturer-recommended solution to the FE, who then implemented it and repeated the measurement. In the uncommon event of a recurring measurement error, it also was keyed into the tablet ODK, the remaining measurements were skipped, the FE stopped using the monitor, and contacted the field supervisor. All malfunctioning monitors and cuffs were immediately withdrawn from fieldwork and replaced.

Using average blood pressure measures as well as self-reported pregnancy status, smoking status, and history of health care provider-diagnosed cardiovascular risk factors, the tablet ODK provided current guideline-based recommendations for (1) follow-up with a health care provider,^{3,4} (2) skipping the blood draw, and / or (3) halting the visit. When mean SBP and DBP did not fall within the same follow-up category, the earlier follow-up was recommended. When mean SBP and DBP warranted follow up within one day, the tablet ODK prompted FEs to immediately terminate the home exam and stay with

respondents for up to 30 minutes while they called a health care provider, friend or relative to discuss the results (occurred in 22 [0.4%] of the 5,381 respondents). As tabulated below in Exhibits 5 and 6, the recommendations differed before and after the 2017-2018 transition between data collection partners.

SBP* (mm Hg)		DBP† (mm Hg)	Risk Factors‡	2016-2017 Follow-up	Blood Draw?	Halt Visit?
(IIIIII IIg)		(IIIIII rig)	ractor3+	rollow-up	Diaw:	VISIL:
<120	AND	<80	NA	2 years	Yes	No
120-139	OR	80-89	NA	1 year	Yes	No
140-159	OR	90-99	NA	2 months	Yes	No
160-179	OR	100-109	NA	1 month	Yes	No
180-199	OR	110-119	Negative	1 week	Yes	No
180-199	OR	110-119	Positive	1 day	No	Yes
>199	OR	>119	NA	1 day	No	Yes

Follow-up based on the Seventh Report of the Joint National Committee on Prevention Detection, Evaluation, and Treatment of High Blood Pressure.³ *Average of SBP #2 & #3 (mm Hg) [Variable: H5SBP]. †Average of DBP #2 & #3 (mm Hg) [Variable: H5DBP]. † Self-reported pregnancy – known or not known [Variable: H5Q012 = 1 or 98] or currently smoke [Variable: H5Q015 = 1] or history of health care provider-diagnosed high blood pressure [Variable: H5Q045A = 1], diabetes [Variable: H5Q045B = 1], heart disease [Variable: H5Q045C = 1], chronic kidney disease [Variable: H5Q045D = 1], stroke [Variable: H5Q045E = 1] or high cholesterol or triglycerides [Variable: H5Q045F = 1]. NA = not applicable.

Exhibit 5. 2016-2017 Recommendations for Follow-up, Blood Draw, and Visit

SBP* (mm Hg)		DBP† (mm Hg)	Risk Factors‡	2018-2019 Follow-up	Blood Draw?	Halt Visit?
<120	AND	<80	NA	1 year	Yes	No
120-129	AND	<80	NA	3-6 months	Yes	No
130-139	OR	80-89	Negative	3-6 months	Yes	No
130-139	OR	80-89	Positive	1 month	Yes	No
140-180	OR	90-120	NA	1 month	Yes	No
>180	OR	>120	NA	1 day	No	Yes

Follow-up based on the Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults from the American Heart Association/American College of Cardiology Task Force. **Average of SBP #2 & #3 (mm Hg) [Variable: H5SBP]. *Average of DBP #2 & #3 (mm Hg) [Variable: H5DBP]. *Self-reported pregnancy – known or not known [Variable: H5Q012 = 1 or 98] or currently smoke [Variable: H5Q015 = 1] or history of health care provider-diagnosed high blood pressure [Variable: H5Q045A = 1], diabetes [Variable: H5Q045B = 1], heart disease [Variable: H5Q045C = 1], chronic kidney disease [Variable: H5Q045F = 1]. NA = not applicable.

Exhibit 6. 2018-2019 Recommendations for Follow-up, Blood Draw, and Visit

FEs transferred the follow-up recommendation to a "Cardiovascular Health Sheet" and gave it to respondents after the home exam. The sheet included the date of the home exam, mean systolic and diastolic blood pressures warranting the follow-up recommendation, information about risk factors for heart disease, and contact information for the American Heart Association.

4.5 Data cleaning

Blood pressure and pulse rate were double keyed, automatically compared, and range checked at the time of entry into the tablet ODK to prevent keystroke errors. They also were plotted over time, statistically summarized, and reviewed weekly throughout Wave V to monitor missing data, outliers, digit preference, and short-term reliability. Moreover, repeated measures were compared for consistency.

5. Constructed Variables

For the following constructed variables that are based on the blood pressure and pulse rate collected three times during the visit, the final calculations were made using measures 2 and 3 whenever possible. When either measure 2 or 3 was missing, the other single measure was used in the calculation. In cases when both measures 2 and 3 were missing, measure 1 was used in the calculation. The variable, called H5BPFLG, flags which measures were used in the construction of each of these calculated variables.

5.1 Average systolic blood pressure (mm Hg) [H5SBP]

Average systolic blood pressure was constructed as the mean of systolic blood pressures 2 and 3. When either measure 2 or 3 was missing, the systolic blood pressure for the other single measure was used. In cases when both measures 2 and 3 were missing, systolic blood pressure 1 was used.

5.2 Average diastolic blood pressure (mm Hg) [H5DBP]

Average diastolic blood pressure was constructed as the mean of diastolic blood pressures 2 and 3. When either measure 2 or 3 was missing, the diastolic blood pressure for the other single measure was used. In cases when both measures 2 and 3 were missing, diastolic blood pressure 1 was used.

5.3 Average pulse rate (beats/min) [H5PR]

Average pulse rate was constructed as the mean of pulse rates 2 and 3. When either measure 2 or 3 was missing, the pulse rate for the other single measure was used. In cases when both measures 2 and 3 were missing, pulse rate 1 was used.

5.4 Pulse pressure (mm Hg) [H5PP]

Pulse pressure was constructed as the average of the difference between systolic and diastolic blood pressures using measures 2 and 3. When either measure 2 or 3 was missing, the difference between systolic and diastolic blood pressure for the other single measure was used. In cases when both

measures 2 and 3 were missing, the difference between the systolic and diastolic blood pressure 1 was used. The formula is:

$$((SBP2 - DBP2) + (SBP3 - DBP3))/2$$

5.5 Mean arterial pressure (mm Hg) [H5MAP]

Mean arterial pressure was conventionally approximated as the weighted sum of systolic and diastolic blood pressure measures 2 and 3, where the weights for SBP (1/3) and DBP (2/3) reflect the typical contributions of ventricular systole and diastole to the duration of the cardiac cycle. When either measure 2 or 3 was missing, the other single measure was used. In cases when both measures 2 and 3 were missing, the first measure was used. The formula is:

$$(((SBP2 + (2*DBP2))/3) + ((SBP3 + (2*DBP3))/3))/2$$

5.6 Blood pressure classification based on JNC7 [H5BPCLS4]

Classification of average blood pressures was based on guidelines from the Seventh Report of the Joint National Committee on Prevention Detection, Evaluation, and Treatment of High Blood Pressure (JNC7).³

JNC7	H5SBP		H5DBP	
Category	(mm Hg)		(mm Hg)	H5BPCLS4
Normal	<120	AND	<80	1
Pre-hypertension	120-139	OR	80-89	2
Hypertension Stage 1	140-159	OR	90-99	3
Hypertension Stage 2	≥ 160	OR	≥ 100	4

Exhibit 7. JNC7 Classification of Blood Pressure

5.7 Blood pressure classification based on AHA/ACC [H5BPCLS5]

Classification of average blood pressures also was based on the Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults from the American Heart Association/American College of Cardiology Task Force (AHA/ACC).⁴

AHA/ACC	H5SBP		H5DBP	
Category	(mm Hg)		(mm Hg)	H5BPCLS5
Normal	<120	AND	<80	1
Elevated	120-129	AND	<80	2
Hypertension Stage 1	130-139	OR	80-89	3
Hypertension Stage 2	140-180	OR	90-120	4
Hypertension Crisis	>180	OR	>120	5

Exhibit 8. AHA/ACC Classification of Blood Pressure

5.8 Antihypertensive medication use [H5AHT]

Use of a prescription medication in the past 4 weeks in one or more of the therapeutic classes listed in Exhibit 9 was assigned a value of 1. Non-use of a prescription medication in the past four weeks in one of the therapeutic classes listed below was assigned a value of 0.

Class	Label	Variable
040-042-***	Angiotensin converting enzyme (ACE) inhibitors	
040-043-***	Anti-adrenergic agents (peripherally acting)	
040-044-***	Anti-adrenergic agents (centrally acting)	
040-046-386	Beta-adrenergic blocking agents	
040-047-***		
040-046-388	Calcium channel blocking agents	H5AHT
040-048-***		
040-049-156	Thiazide diuretics	
040-053-***	Vasodilators	
040-055-***	Antihypertensive Combinations	
040-056-***	Angiotensin II (AT2) inhibitors	

Exhibit 9. Antihypertensive Medication Use

Therapeutically classified use of prescription medication in particular classes may confound biomarker-based estimates of disease prevalence or risk. For example, use of antihypertensive medications may confound blood pressure-based estimates of hypertension prevalence or cardiovascular disease risk. However, the (1,0) classifications should be used cautiously in the investigation or control of potential confounding, because selection biases often threaten the study of non-randomized medication exposures.

5.9 Joint Classification of Hypertension [**H5HTENJC**]

Respondents were flagged as having evidence of hypertension when they met **at least one** of the following criteria in Exhibit 10:

Criterion (≥ 1 of the following must be true)	Variable & Value
JNC7 Hypertension Stage 1 or 2	H5BPCLS4=3 or 4
Self-reported history of diagnosed high blood pressure	H5Q045A=1
Antihypertensive medication use in the past 4 weeks	H5AHT=1

Exhibit 10. Criteria Used to Identify Hypertension

The criteria are analogous to those adopted at Wave IV,^{5,6} in that they *rely only on contemporaneous information collected at the home exam and the JNC classification*.

6. Quality Control

6.1. Equipment Evaluation and Accuracy

To ensure it was in working order, all field equipment was evaluated before study start-up in 2016 and during the 2017-2018 transition between data collection partners.

6.2. Digit Preference

FE-specific digit preference was monitored throughout fieldwork using a Pearson χ^2 test of the null hypothesis that all possible digits (0, 1, 2, ..., 9) were observed with equal frequency and a digit preference score (DPS).⁷ As at Add Health Wave IV, there was little evidence of penultimate digit preference in FE recording of measured arm circumference (DPS: 1.9) or terminal digit preferences in recording of blood pressures or pulse rates (DPS range: 1.9–3.5). There was, however, some evidence of whole- and half-unit rounding of terminal digits for arm circumferences despite FE training aimed at eliminating it (DPS: 65.3).⁸

6.3. Reliability

Within a race/ethnicity- and sex-stratified random sample of 112 Add Health respondents among whom cardiovascular measures were collected twice, on average 14.1 (95% confidence interval: 13.0–15.3) days apart, typically by the same FE and at approximately the same time of day, the reliability of arm circumference, blood pressures and pulse rates was estimated as an intra-class correlation coefficient (ICC, 95% confidence interval) (Exhibit 11). The estimates (range: 0.65–0.86) reflected those stemming from Add Health Wave IV and suggested that home exam cardiovascular measures are comparably reliable at Add Health Wave V.8

Measure	N	ICC	95% CI
Arm (cm)	112	0.86	(0.82,0.91)
SBP #1	111	0.72	(0.62,0.81)
SBP #2	112	0.65	(0.54,0.75)
SBP #3	112	0.70	(0.60,0.79)
Average SBP	112	0.72	(0.64,0.81)
DBP #1	111	0.71	(0.62,0.80)
DBP #2	112	0.67	(0.56,0.77)
DBP #3	112	0.67	(0.57,0.77)
Average DBP	112	0.71	(0.62,0.80)
PR #1	111	0.69	(0.60,0.79)
PR #2	112	0.67	(0.56,0.77)
PR #3	112	0.70	(0.60,0.79)
Average PR	112	0.72	(0.63,0.81)

Exhibit 11. Reliability of cardiovascular measures

7. The Cardiovascular Data File (bcardio5.xpt)

7.1. Structure

The structure of the disseminated cardiovascular data file is flat. This means that it is a respondent-level data file, wherein each respondent has one and only one record. The respondent identifier (AID) will appear in the data file only once.

7.2. Contents

The cardiovascular data file includes the variables below, which are described in the corresponding codebook documentation that also contains frequencies.

Variable Name	Variable Description
AID	Respondent Identifier
H5Q015	Q015 Currently smoke tobacco products
H5ARM	Q023 Which arm is measured
H5ARMCIR	Measured arm circumference (cm)
H5ARMINS	Flag indicates arm measure was converted from inches to cms
H5CUFFIT	Flag indicates if the arm fit the BP cuff
H5Q031	Q031 Systolic blood pressure #1 (MMHg)
H5Q032	Q032 Diastolic blood pressure #1 (MMHg)
H5Q033	Q033 Pulse rate #1 (/Min)
H5Q036	Q036 Systolic blood pressure #2 (MMHg)
H5Q037	Q037 Diastolic blood pressure #2 (MMHg)
H5Q038	Q038 Pulse rate #2 (/Min)
H5Q041	Q041 Systolic blood pressure #3 (MMHg)
H5Q042	Q042 Diastolic blood pressure #3 (MMHg)
H5Q043	Q043 Pulse rate #3 (/Min)
H5BPFLG	Number of BP/PR measures used to for single measure
H5SBP	Average systolic blood pressure (MMHg)
H5DBP	Average diastolic blood pressure (MMHg)
H5BPCLS5	Blood pressure classification based on AHA/ACC
H5BPCLS4	Blood pressure classification based on JNC7
H5PR	Average pulse rate (/Min)
H5PP	Pulse pressure (MMHg)
H5MAP	Mean arterial pressure (MMHg)
H5Q045A	Q045a Ever diagnosed with high blood pressure or hypertension
H5Q045B	Q045b Ever diagnosed with diabetes
H5Q045C	Q045c Ever diagnosed with heart attack or heart surgery
H5Q045D	Q045d Ever diagnosed with kidney disease or failure
H5Q045E	Q045e Ever diagnosed with stroke or mini-stroke
H5Q045F	Q045f Ever diagnosed with high cholesterol or triglycerides
H5AHT	Flag indicates antihypertensive medication use in past 4 weeks
H5HTENJC	Hypertension joint classification

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