

2022 Add Health Users Conference

Add Health Wave V Biological Data and Vital Events

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10:15-11:45 AM

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Add Health Wave V

- Biological Data
- Vital Events

Wave V Biological Data – Choice

- Conditions prevalent among young-to-middle aged U.S. adults
- Processes by which they are associated with future health
- Measures characterizing those processes
- Feasibility of field collection across U.S.
- Availability of data across waves
- Reliability & validity of results

Wave V Biological Data – Domains

- Cardiovascular
- Anthropometric
- Metabolic
- Inflammatory
- Renal
- Omic
- Pharmacologic
- Other

Wave V Biological Data – Measures

Biological Data Domains and Measures

Cardiovascular	SBP [mmHg]
	DBP [mmHg]
	PR [beats/min]
Anthropometric	Weight [kg]
	Height [cm]
	Waist Circumference [cm]
	Arm Circumference [cm]
Metabolic	Hb _{A1c} [%]
	Glucose [mg/dl]
	TC [mg/dL]
	HDL-C [mg/dL]
	TG [mg/dL]
Inflammatory	hsCRP [mg/L]
Renal	Creatinine [mg/dL]
	Cystatin C [mg/L]
Omic	Transcriptome
	Microbiome
	Epigenome
Pharmacologic	Medication Use

DBP = diastolic blood pressure. Hb_{A1c} = hemoglobin A1c.
HDL-C = high-density lipoprotein cholesterol. PR = pulse
rate. SBP = systolic blood pressure. TC = total cholesterol.
TG = triglycerides.

Wave V Biological Data – Measures

- Cardiovascular
 - Primary
 - systolic blood pressure (SBP)
 - diastolic blood pressure (DBP)
 - pulse rate (PR)
 - Secondary
 - pulse pressure ($PP = SBP - DBP$)
 - mean arterial pressure ($MAP = [SBP + 2 \times DBP] \div 3$)

Wave V Biological Data – Classification

- Cardiovascular

- SBP/DBP according to JNC 7 guidelines*

< 120/80 mm Hg	Normal
120-139/80-89 mm Hg	Pre-Hypertension
140-159/90-99 mm Hg	Stage 1 Hypertension
≥ 160/100 mm Hg	Stage 2 Hypertension

- SBP/DBP according to ACC/AHA guidelines†

< 120/80 mm Hg	Normal
120-129/<80 mm Hg	Elevated
130-139/80-89 mm Hg	Stage 1 Hypertension
≥ 140/90 mm Hg	Stage 2 Hypertension



NEW!

Wave V Biological Data – Measures

- Anthropometric
 - Primary
 - weight
 - height
 - waist circumference (waist)
 - arm circumference (arm)
 - Secondary
 - body mass index ($\text{BMI} = \text{weight in kg} / \text{height in m}^2$)

Wave V Biological Data – Classification

- Anthropometric
 - Waist according to NHLBI Evidence Report*
 - ≤ 88 (102) cm in ♀ (♂) Lower Risk
 - > 88 (102) cm in ♀ (♂) High Risk
 - BMI according to NHLBI Evidence Report*
 - < 18.5 kg/m² Underweight
 - 18.5-24.9 kg/m² Normal
 - 25.0-25.9 kg/m² Overweight
 - 30.0-34.9 kg/m² Obesity, Stage I
 - 35.0-39.9 kg/m² Obesity, Stage II
 - ≥ 40.0 kg/m² Obesity, Stage III

Wave V Biological Data – Measures

- Metabolic, lipids*
 - Primary
 - total cholesterol (TC)
 - high density lipoprotein cholesterol (HDL-C)
 - triglycerides (TG)
 - Secondary
 - low density lipoprotein cholesterol ($\text{LDL-C} = \text{TC} - \text{HDL-C} - \text{TG} \div 5$)†
 - TC:HDL-C ratio ($= \text{TC} / \text{HDL-C}$)
 - non-HDL-C ($= \text{TC} - \text{HDL-C}$)

Wave V Biological Data – Classification

NEW!

- Metabolic, lipids*

- According to NCEP ATP III guidelines†

• TC (mg/dl)	< 200	desirable
	200-239	borderline high
	≥ 240	high
• HDL-C (mg/dl)	< 40	low
	≥ 60	high
• LDL-C (mg/dl)	< 100	optimal
	100-129	near optimal
	130-159	borderline high
	160-189	high
	≥ 190	very high
• TG‡ (mg/dl)	< 150	normal
	150-199	borderline high
	200-499	high
	≥ 500	very high

- According to AHA/ACC guidelines||

• LDL-C (mg/dl)	160-189	moderate
	≥ 190	severe hypercholesterolemia
• TG‡ (mg/dl)	175-499	moderate
	≥500	severe hypertriglyceridemia

Wave V Biological Data – Measures

- Metabolic, glucose homeostasis*
 - glucose
 - glycosylated hemoglobin (HbA1c)

Wave V Biological Data – Classification

- Metabolic, glucose homeostasis*
 - According to ADA guidelines†
 - fasting glucose (mg/dl)
 - ≤ 99 normal
 - 100-125 impaired
 - ≥ 126 diabetes
 - non-fasting glucose (mg/dl)
 - ≥ 200 diabetes
 - HbA1c (%)
 - 5.7-6.4 increased risk for diabetes
 - ≥ 6.5 diabetes

Wave V Biological Data – Measures

- Inflammatory
 - high sensitivity C-reactive protein (hsCRP)

Wave V Biological Data – Classification

- Inflammatory
 - hsCRP according to CDC / AHA guidelines*

< 1 mg/L	low
1-3 mg/L	average
> 3 mg/L	high
> 10 mg/L	must trigger searches for factors capable of confounding hsCRP-based risk estimates

Wave V Biological Data – Measures



- Renal
 - Primary
 - creatinine
 - cystatin c
 - Secondary
 - estimated glomerular filtration rate (eGFR in ml/min/1.73 m²)*
 $= 141 \times \min(\text{Scr}/\kappa, 1)^\alpha \times \max(\text{Scr}/\kappa, 1)^{-1.209} \times 0.993^{\text{Age}} [\times 1.018 \text{ if } \text{♀}] [\times 1.159 \text{ if black}],$
where:
 - Scr = serum creatinine
 - $\kappa = 0.7 (\text{♀}) \text{ or } 0.9 (\text{♂})$
 - $\alpha = -0.329 (\text{♀}) \text{ or } -0.411 (\text{♂})$
 - analogous formulas for Scys & Scr-cys
 - newer NKF/ASN-endorsed equations include both, omit race & are most accurate

Wave V Biological Data – Classification

- Renal
 - eGFR according to KDIGO guidelines*

≥ 90 ml/min/1.73 m ²	Normal or high (G1)
60-89	Mildly decreased (G2)*
45-59	Mildly to moderately decreased (G3a)
30-44	Moderately to severely decreased (G3b)
15-29	Severely decreased (G4)
<15	Kidney failure (G5)

Wave V Biological Data – Measures

- Pharmacologic
 - prescription medications
 - select over-the-counter medications (salicylates & NSAIDS)

Wave V Biological Data – Classification

- Pharmacologic
 - prescriptions according to Multum Lexicon Plus®
 - example therapeutic classes
 - antihypertensives
 - antihyperlipidemics
 - antidiabetics
 - anti-inflammatories
 - narcotics
 - antidepressants
 - antipsychotics
 - anxiolytics
 - anticonvulsants



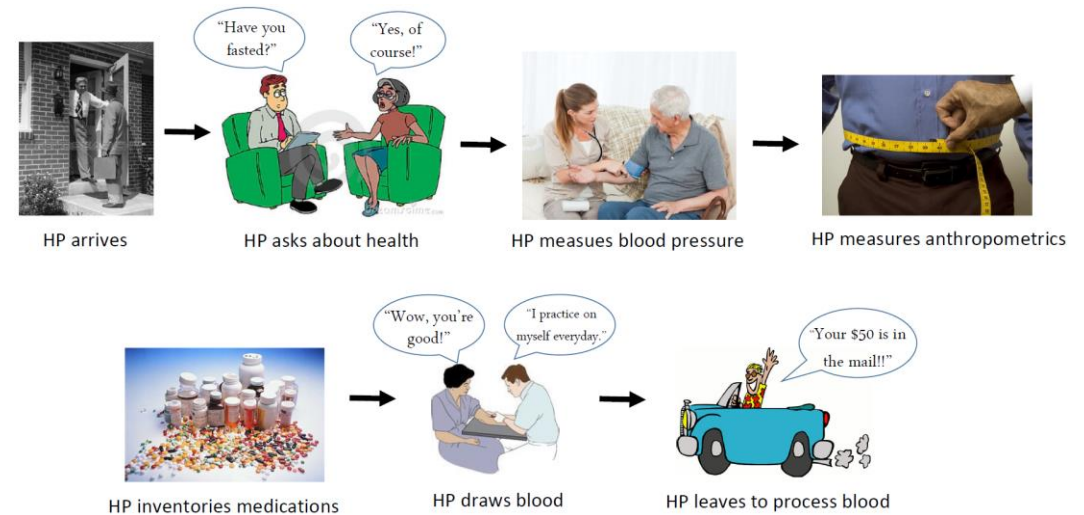
Wave V Biological Data – Measures



- Other
 - Additional Inflammatory/Immune
 - IL-1B, 6, 8 & 10
 - Tumor Necrosis Factor (TNF- α)
 - Cytomegalovirus (CMV)
 - Hepatic
 - Aspartate Aminotransferase (AST)
 - Alanine Aminotransferase (ALT)
 - AST:ALT Ratio
 - Neurodegeneration
 - Neurofilament Light Chain (NfL)
 - Tau

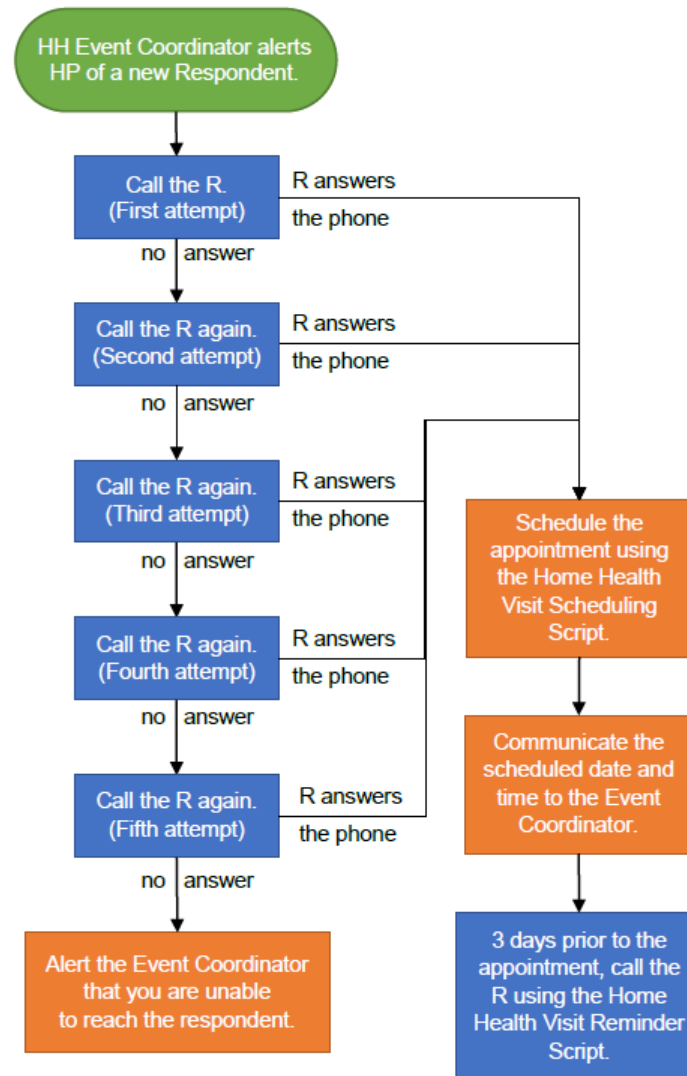
Wave V Biological Data – Collection

- Scheduling
- Preparation
- Interview
- Examination
- Medication Inventory
- Phlebotomy
- Processing
- Data Upload



Wave V Biological Data – Collection

- Scheduling



Wave V Biological Data – Collection

- Scheduling

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	✓	✓*	✓*	✓*	✓*	✓	✗
Afternoon	✓	✓*	✓*	✓*	✓	✓	✗
Evening	✓	✓	✓	✓	✗	✗	✗

- ✓* Preferred – if able to meet *same day* FedEx cutoff
✓ Acceptable – if able to meet *next day* FedEx cutoff
✗ Not Acceptable

Wave V Biological Data – Collection

• Preparation

Home visit equipment and supply list

- Photo ID Badge
- Samsung Galaxy 4 Tablet with power cord
- Microlife blood pressure unit with medium and large cuff
- Spare batteries for blood pressure unit (4 X AA)
- SECA circumferential tape measure
- Metal tape measure
- Carpenter's square
- Health-o-Meter weight scale
- Spare batteries for Health-o-Meter scale (2 X CR2032)
- Cooler/ice packs for cooling samples until centrifugation
- Job Aid Documents
- Pens and Sharpies
- EMSI supplied respondent contact and information sheet
- Pre-printed Post-It notes
- Biohazard bag
- Cardiovascular Health Fact Sheet
- Respondent Fact Sheet
- Protective cover (Chux) for table top (examiner supplied)
- Sharps Container (examiner supplied)

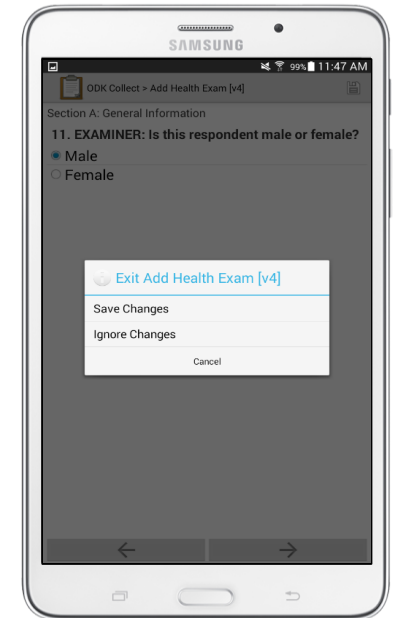
Prepackaged home visit kit

- Vacutainer holder
- 21 gauge needle
- Nitrile gloves
- 2" x 2" gauze pad
- Bandage
- Tourniquet
- 5 or 6 Vacutainer tubes *** The 6th Vacutainer tube (6ml sodium fluoride tube) is required only if respondent's appointment information indicates it is to be collected.
- Biohazard Ziploc bag
- Alcohol prep pad
- Pipettes
- Transport tubes
- 4 Loose Barcode Labels [for shipping manifest, paper version of questionnaire (if needed), glucose transport tube (if needed), and one extra] □ Styrofoam container
- FedEx mailing pouch




Wave V Biological Data – Collection

- Interview & Examination
 - Relied on a Samsung Tablet to
 - guide interview & exam
 - record self-reported health status
 - record physical measurements
 - tailor follow-up recommendations
 - inventory / code medications
 - guide biospecimen processing & shipping
 - control data quality (range checks; double entry)
 - transmit data




Wave V Biological Data – Collection

- Examination
 - Cardiovascular equipment

Measure	Equipment	Pictures	Specifications
Arm	Seca 200 Circumference Tape Measure		200 cm maximum 2-sided cm scaling 1 mm graduations fiberglass tape Add Health-validated* plastic case automatic roll-up end-peg positioner 90 x 25 x 65 mm 50 g < \$13

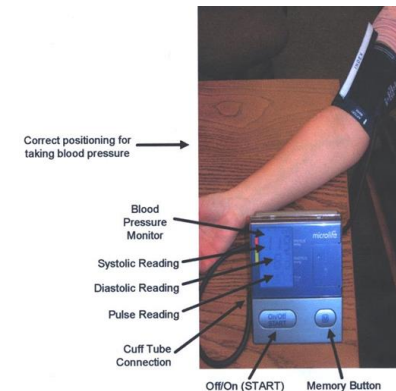
Wave V Biological Data – Collection

- Examination
 - Cardiovascular equipment

Measures	Equipment	Picture	Specifications
SBP DBP PR	MicroLife 3MC1-PC_IB Oscillometric BP Monitor		30-280/40-200 BP/PR range 1-unit graduations 198 measure recall ± 3 mmHg accuracy ± 5 beat pulse accuracy BHS-approved Add Health-validated* 4 "AA" battery-powered w/ AC adapter + USB cable 2 cuffs (24-41 cm) 160 x 140 x 98 mm 735 g (w/ batteries) < \$65



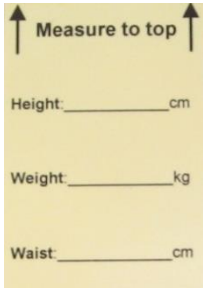
Wave V Biological Data – Collection

- Examination
 - Cardiovascular protocol*
 - trained, certified staff
 - resting, seated respondents
 - arm @ level of heart
 - cuff matched to arm circumference
 - measured SBP, DBP & PR
 - - 3x @ 30 sec intervals
 - - double entered
 - - automatically averaged over last 2
 - provide results, follow-up recs




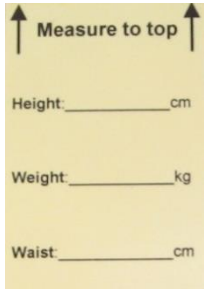
Wave V Biological Data – Collection

- Examination
 - Anthropometric equipment

Measure	Equipment	Pictures	Specifications
Height	Carpenter's Square		portable light weight inexpensive true 90° angle
	Tape Measure		10 ft steel tape
	Post-it Notes		adherent pre-labeled


Wave V Biological Data – Collection

- Examination
 - Anthropometric equipment

Measure	Equipment	Pictures	Specifications
Weight	Health-O-Meter 844KL High Capacity Digital Scale	 	4-point load cell digital display in lb / kg 440 lb maximum 0.1 lb graduations Add Health-validated* long life Li ⁺⁺ battery low battery warning 1-year warranty 12.6 x 12.6 in 4.5 lb < \$70

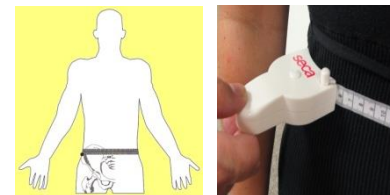
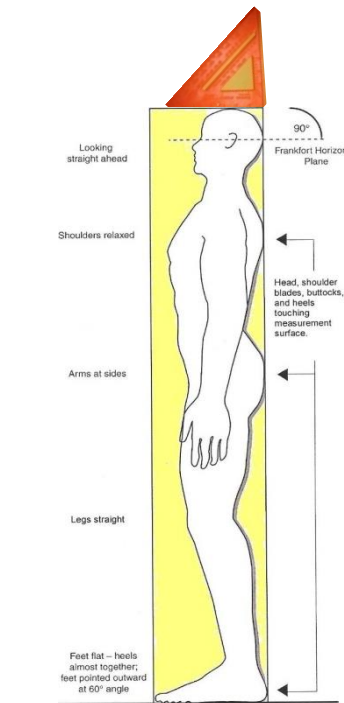
Wave V Biological Data – Collection

- Examination
 - Anthropometric equipment

Measure	Equipment	Pictures	Specifications
Arm	Seca 200 Circumference Tape Measure		200 cm maximum 2-sided cm scaling 1 mm graduations fiberglass tape Add Health-validated* plastic case automatic roll-up end-peg positioner 90 x 25 x 65 mm 50 g < \$13

Wave V Biological Data – Collection

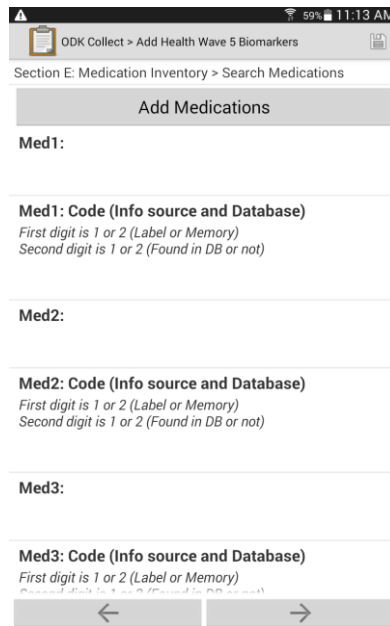
- Examination
 - Anthropometric protocol
 - trained, certified staff
 - dressed, unshoed respondents
 - standing on uncarpeted floor
 - measured
 - height to nearest 0.5 cm
 - weight to nearest 0.1 kg
 - waist to nearest 0.5 cm
 - @ superior border of iliac crest
 - @ end expiration
 - horizontal to floor
 - hair/shoe height to nearest 0.5 cm, as needed



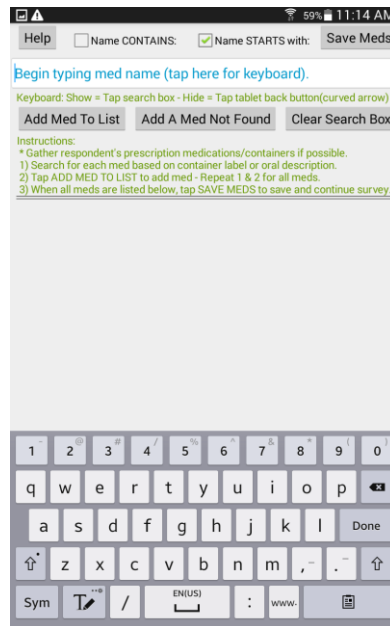
Wave V Biological Data – Collection

- Medication Inventory
 - Protocol

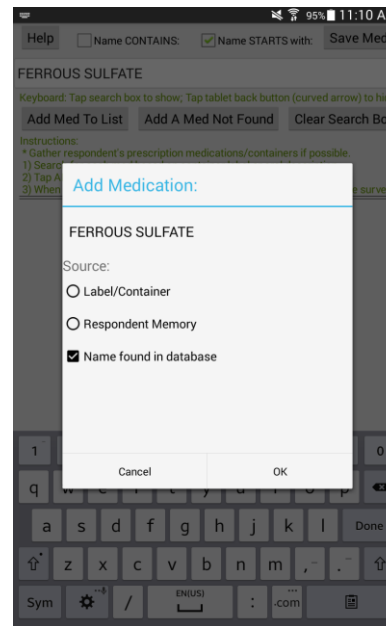
Start Inventory



Enter Meds



Enter Sources



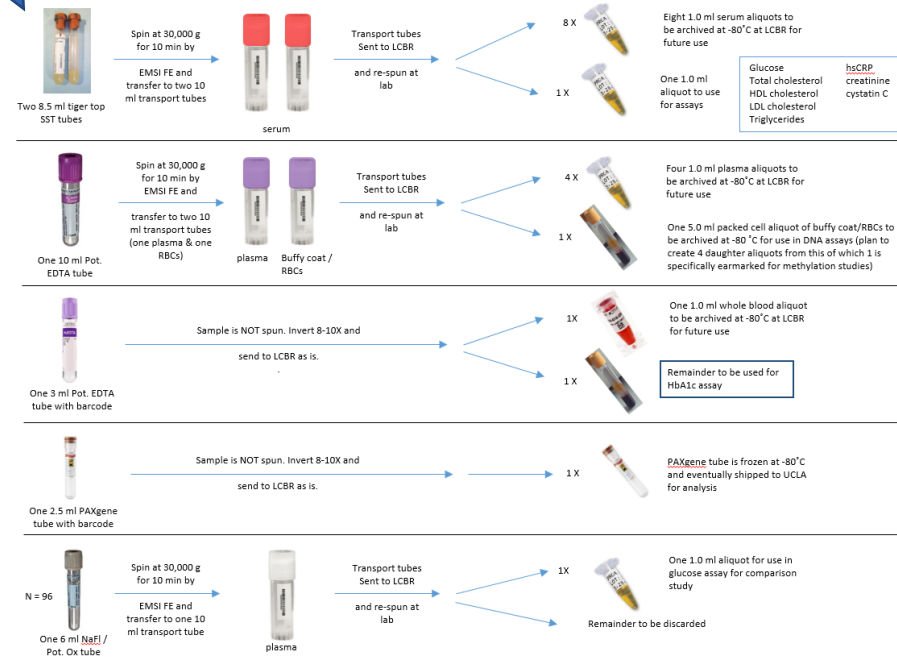
Wave V Biological Data – Collection



• Phlebotomy & Processing

• Protocol

- trained, certified phlebotomists
- fasting (ideally) respondents
- draw blood
- centrifuge
- package
- ship
- assay @ LCBR
- return results

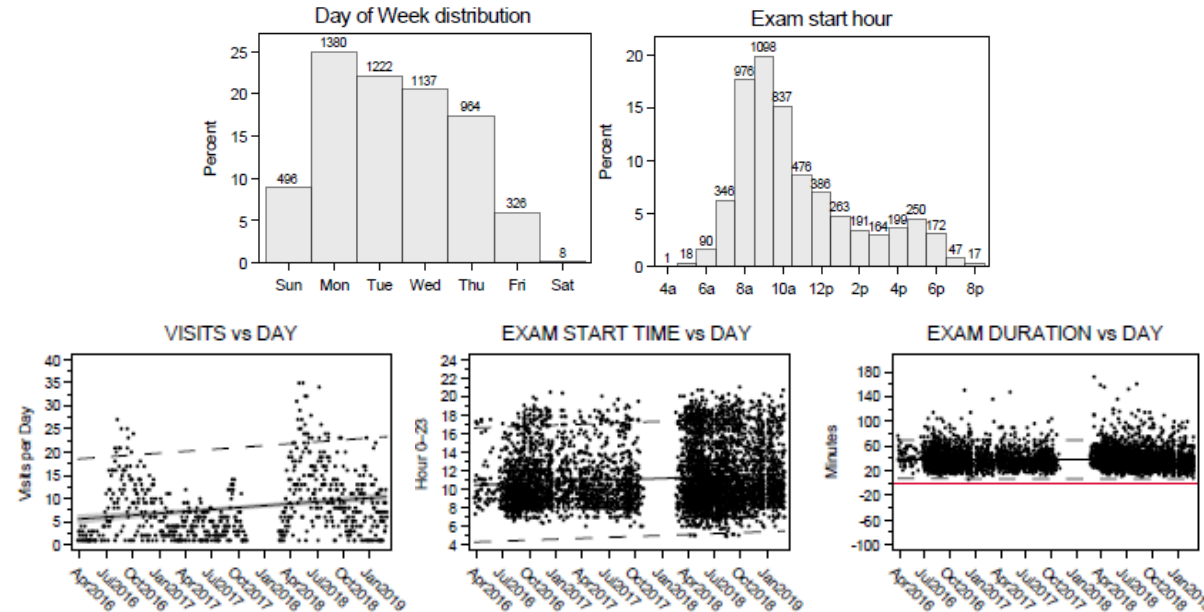


Wave V Biological Data – Key Results

- Overall
 - Surveyed 12,300
 - Consented 8,379 (68%)
 - Examined 5,381 (64%)

Wave V Biological Data – Key Results

- Overall
(unweighted)

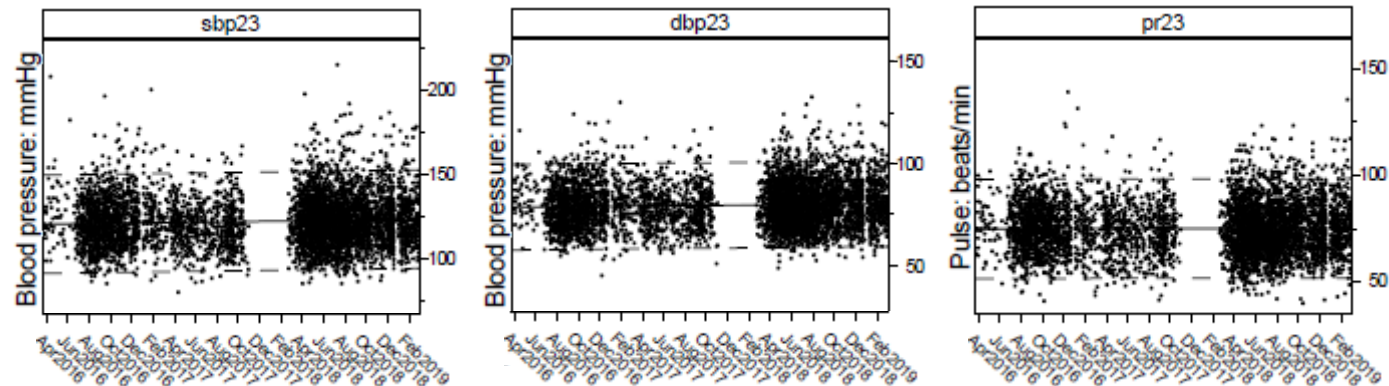


Variable	Mean	SD	P25	P50	P75
Visits / Day	8.1	6.7	3.0	6.0	12.0
Start Time (0-23)	11.1	3.2	8.9	10.1	12.7
Duration (min)	37.8	18.2	28.0	35.0	44.3
Fasting (hr)	9.5	5.9	3.6	11.2	13.7

Wave V Biological Data – Key Results

- Cardiovascular

(unweighted)



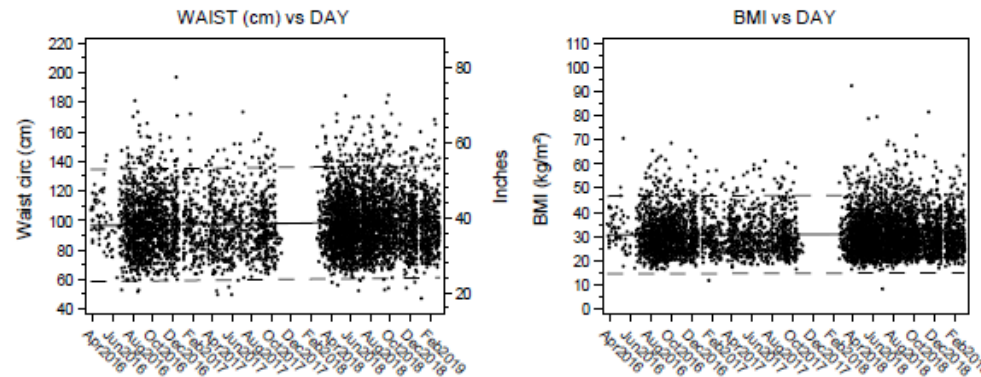
Variable	Mean	SD	P25	P50	P75	P90	P95
SBP (mm Hg)	123	15	113	122	131	141	148
DBP (mm Hg)	79	11	72	79	86	93	98
PR (b/min)	75	12	67	74	83	91	95

} 49% \geq 130/80 (Stage 1)
19% \geq 140/90 (Stage 2)

— 9% \leq 60 (Bradycardia)
3% \geq 100 (Tachycardia)

Wave V Biological Data – Key Results

- Anthropometric
(unweighted)

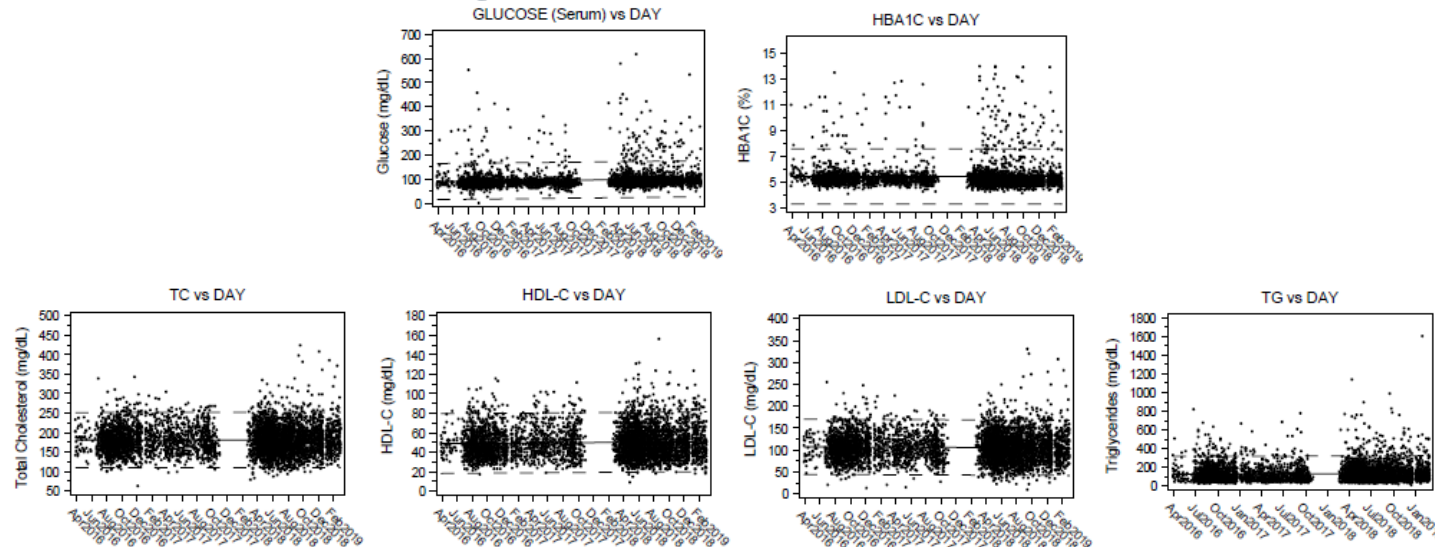


Variable	Mean	SD	P25	P50	P75	P90	P95
Waist (cm)	97.7	19.0	84.0	96.0	109.0	123.0	133.0
BMI (kg/m ²)	30.7	7.8	24.9	29.2	34.7	41.2	45.9

} 51% > 88♀ or 102♂ (High Risk)
75% > 25 (Overweight or Obese)

Wave V Biological Data – Key Results

- Metabolic
(unweighted)



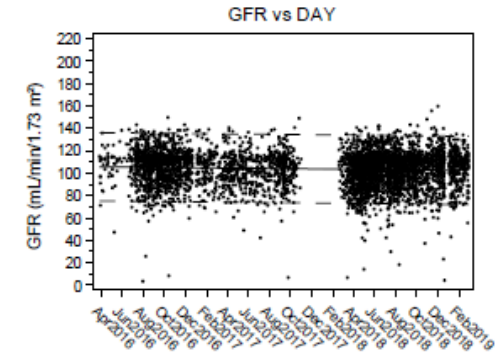
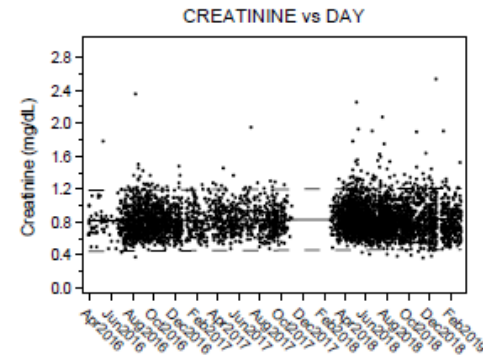
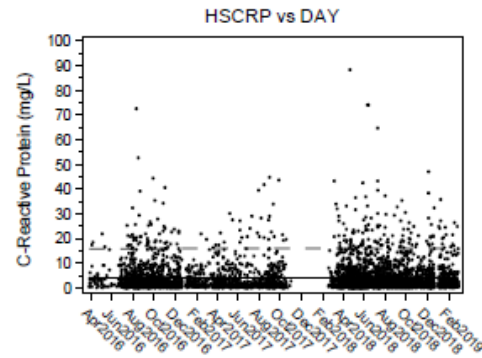
Variable	Mean	SD	P25	P50	P75	P90	P95
Glucose (mg/dl)	95	36	82	89	97	110	132
HbA1c (%)	5.4	0.9	5.0	5.2	5.4	5.7	6.3
TC (mg/dl)	181	36	156	177	202	227	242
HDL-C (mg/dl)	50	15	39	47	58	70	78
LDL-C (mg/dl)	106	32	84	103	125	146	160
TG (mg/dl)	129	95	71	102	156	237	298

3.9% ≥ 126 or 200 (Diabetes)
4.6% ≥ 6.5 (Diabetes)

5.1% ≥ 160 (Hypercholesterolemia)
20% ≥ 175 (Hypertriglyceridemia)

Wave V Biological Data – Key Results

- Inflammatory & Renal
(unweighted)



Variable	Mean	SD	P25	P50	P75	P90	P95
hsCRP (mg/L)	4.1	6.3	0.8	1.8	4.7	9.8	16
Creatinine (mg/dl)	0.8	0.4	0.7	0.8	0.9	1.1	1.2
	Mean	SD	P5	P10	P25	P50	P75
GFR (ml/min/1.73m ²)	104	16	77	83	94	106	113

— 20% > 3 (High)

— 19% < 90 (Decreased)
0.7% < 60 (CKD or ESKD)

Wave V Biological Data – Key Results

- Pharmacologic
 - Prescription medication use, by therapeutic class
 - antihypertensives 12.1%
 - antihyperlipidemics 3.8%
 - antidiabetics 4.8%
 - NSAID/salicylate 5.5%
 -
 -
 -

Wave V Biological Data – Key Results

- Other
 - Inflammatory/Immune
 - Hepatic
 - Neurodegeneration

Pending!

Wave V Biological Data – Quality

- Threats
 - poorly trained or monitored staff
 - departures from standardized protocol
 - use of heterogeneous, untested equipment
 - reliance on manual processes
 - missing data
 - measurement error
 - trend / cyclicity
 - digit preference
 - inaccuracy
 - unreliability

Wave V Biological Data – Quality

- Control
 - uniformly train & monitor staff
 - follow standardized protocol
 - use standard, tested equipment
 - automate processes
 - track / reduce missing data
 - track / reduce measurement error
 - trend / cyclicity
 - digit preference
 - inaccuracy
 - unreliability

Wave V Biological Data – Quality

- Reliability

Race / Ethnicity	Sex	Intra-Individual Variation Sub-Study*
White	Male	12
	Female	12
Black	Male	12
	Female	12
Hispanic	Male	12
	Female	12
Other	Male	12
	Female	12
Total		96

*Involved examining participants 2x, 1-3 weeks apart, on ~ same day of week @ same time of day.

Wave V Biological Data – Quality

- Reliability

MEASURE	N	ICC	(95% CI)
SBP23	112	0.72	(0.64,0.81)
DBP23	112	0.71	(0.62,0.80)
PR23	112	0.72	(0.63,0.81)
Arm	112	0.88	(0.82,0.91)
Height	110	0.95	(0.93,0.97)
Weight	110	1	(1.00,1.00)
Waist	109	0.96	(0.94,0.97)
BMI	110	0.98	(0.98,0.99)
GLUCOSE	103	0.94	(0.91,0.96)
HBA1C	101	0.99	(0.99,0.99)
TG	103	0.63	(0.51,0.74)
TC	103	0.88	(0.84,0.92)
HDL-C	103	0.95	(0.94,0.97)
LDL-C	103	0.86	(0.81,0.91)
HSCRP	94	0.82	(0.75,0.89)
CREATININE	103	0.93	(0.91,0.96)
CYSTATIN-C	103	0.86	(0.81,0.91)
GFR	103	0.89	(0.85,0.93)

*The corresponding agreement (95% CI) between therapeutic classified prescription medications = 85% (79%-92%), kappa coefficient (95% CI) = 0.82 (0.71-0.93).

Wave V Vital Events

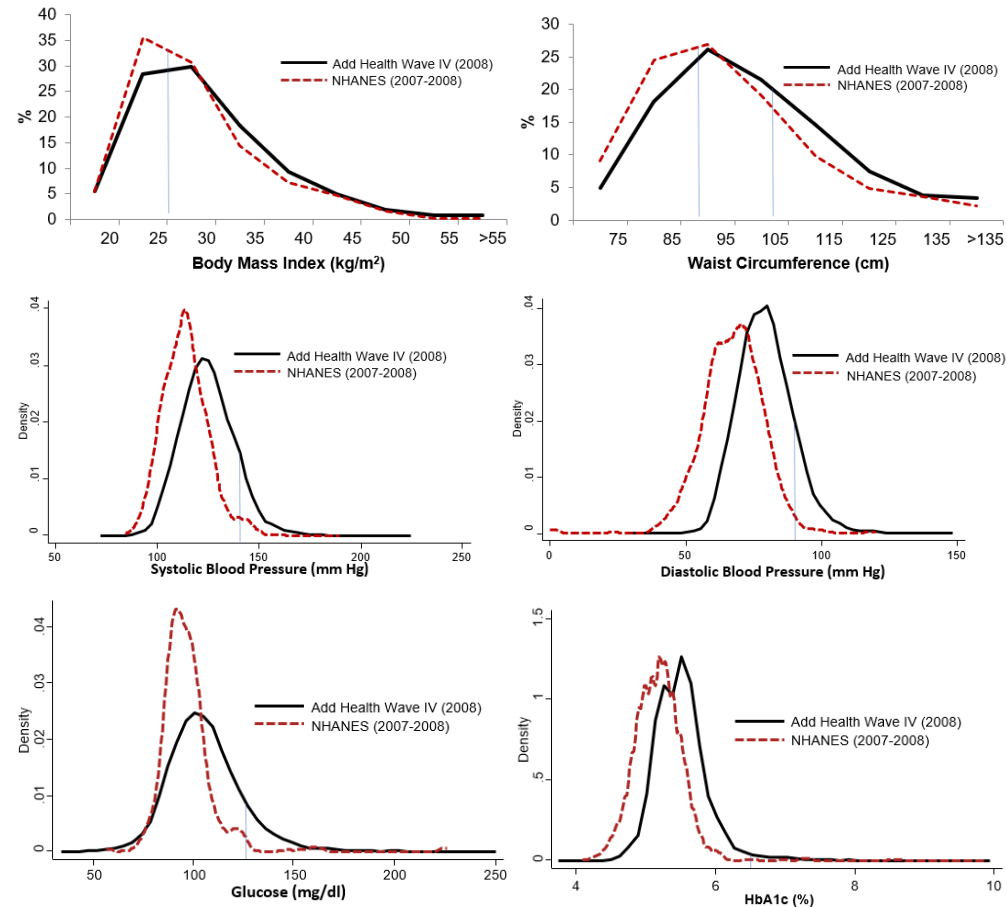
Wave V Vital Events

- Rationale
- Surveillance
 - Tracing, Screening & Matching
 - Investigation & Abstraction
 - Review, Classification & Adjudication
- Results
- Quality



Wave V Vital Events – Rationale

Risk Factor Distributions @ Wave IV

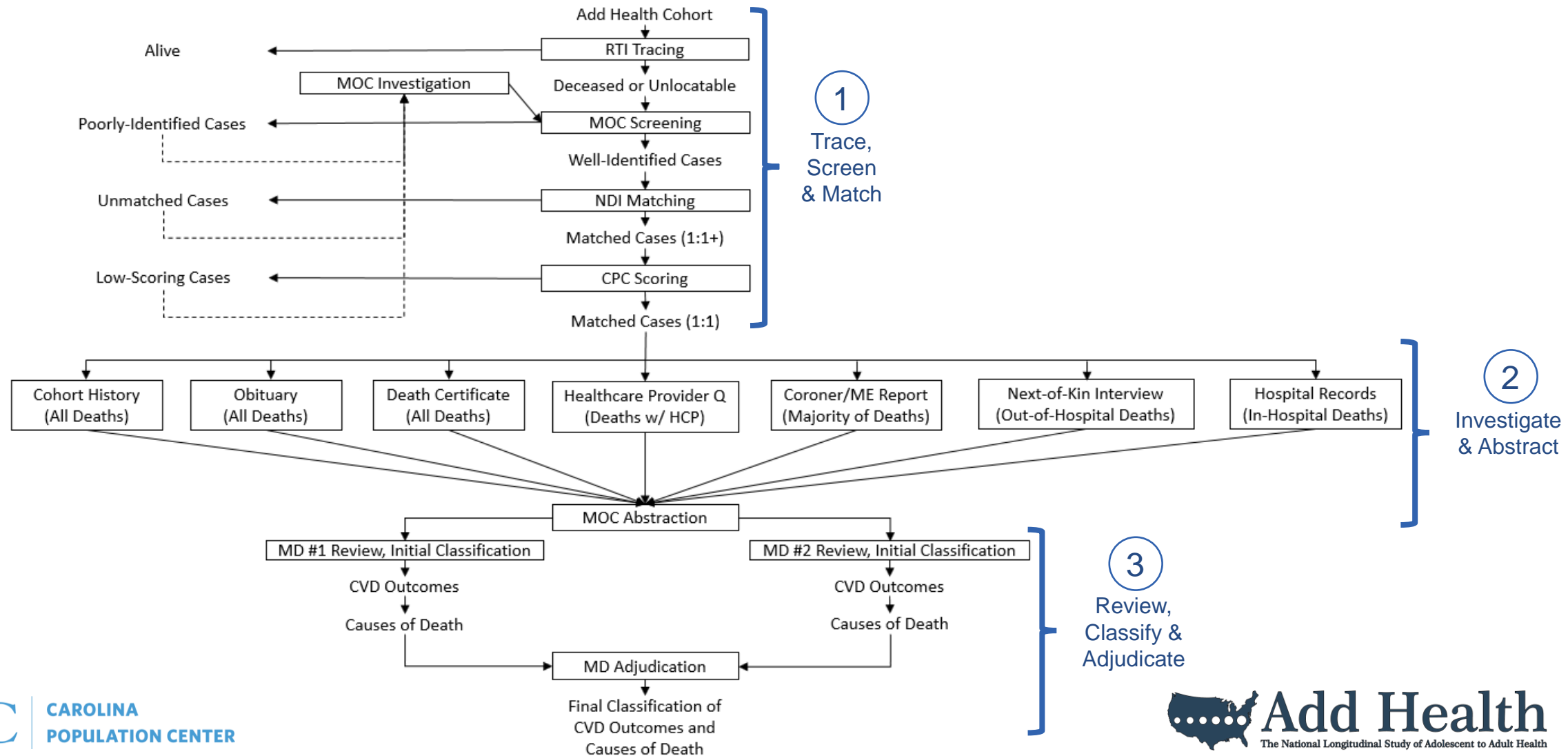


Epidemiology 2011;22(4):532.
Ann Epidemiol 2014;24(12):903.
Demogr Res 2015;32:1081.

Wave V Vital Events - Goal

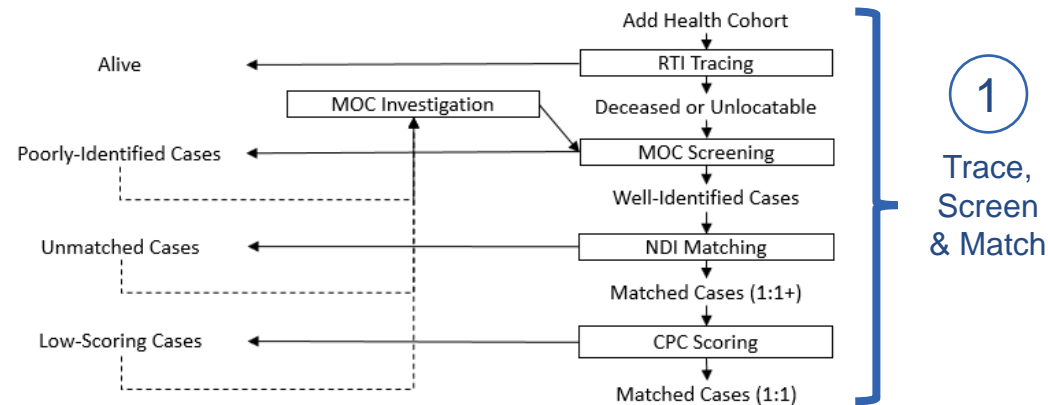
- To establish a scalable infrastructure for surveillance of chronic disease events, initially by ascertaining decedents
- To anticipate the epidemiologic transition to rapid increases in chronic disease morbidity and mortality with age
- To do so under “*The Biology of Chronic Disease Emergence and Medical Outcomes Surveillance*” (Wave V Project 5096; P01-HD031921)

Wave V Vital Events – Surveillance



Wave V Vital Events – Results

- Tracing, Screening & Matching

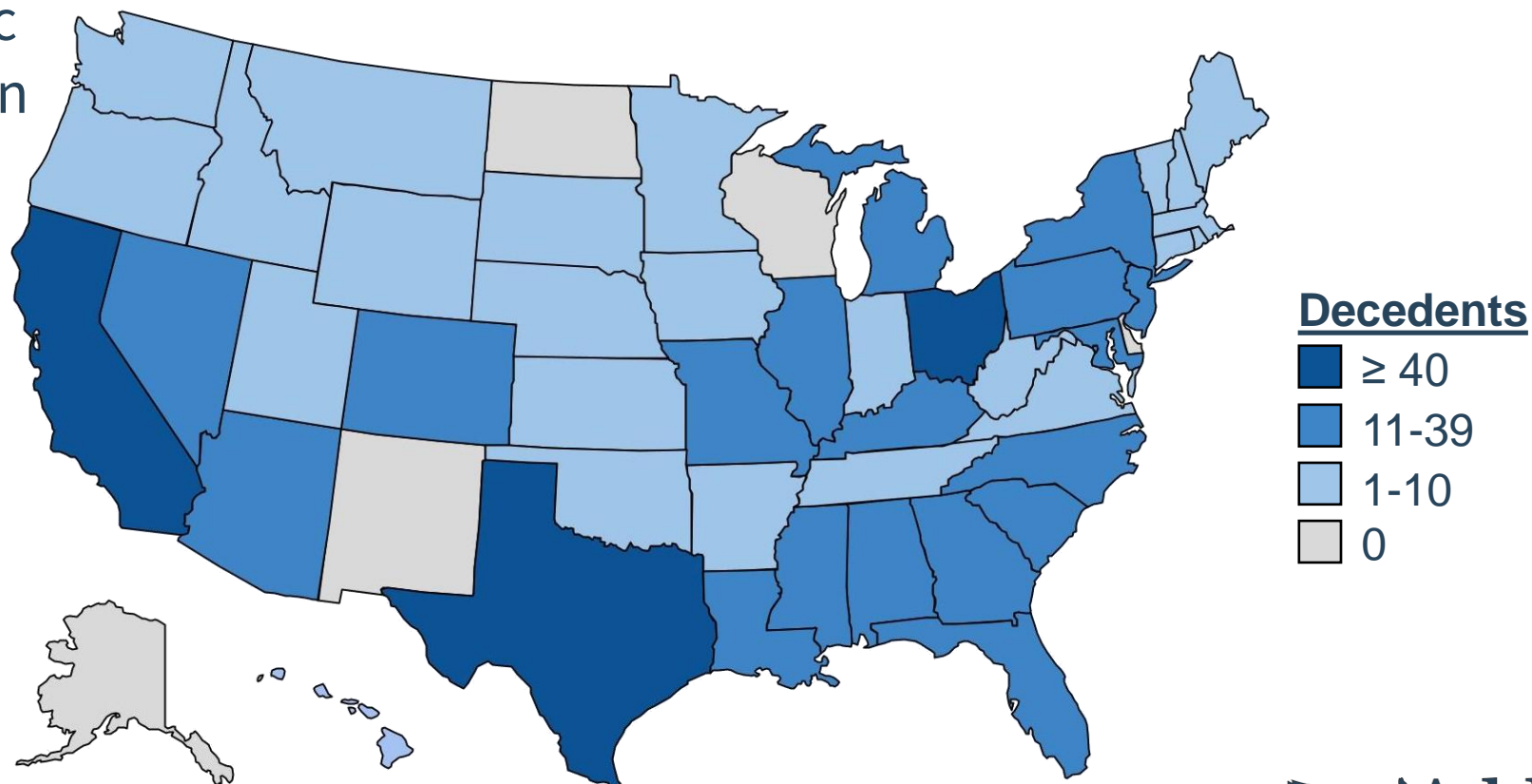


640 of 641 Decedents Matched 1:1

NDI 1994-2020 & 2021 (preliminary)

Wave V Vital Events – Results

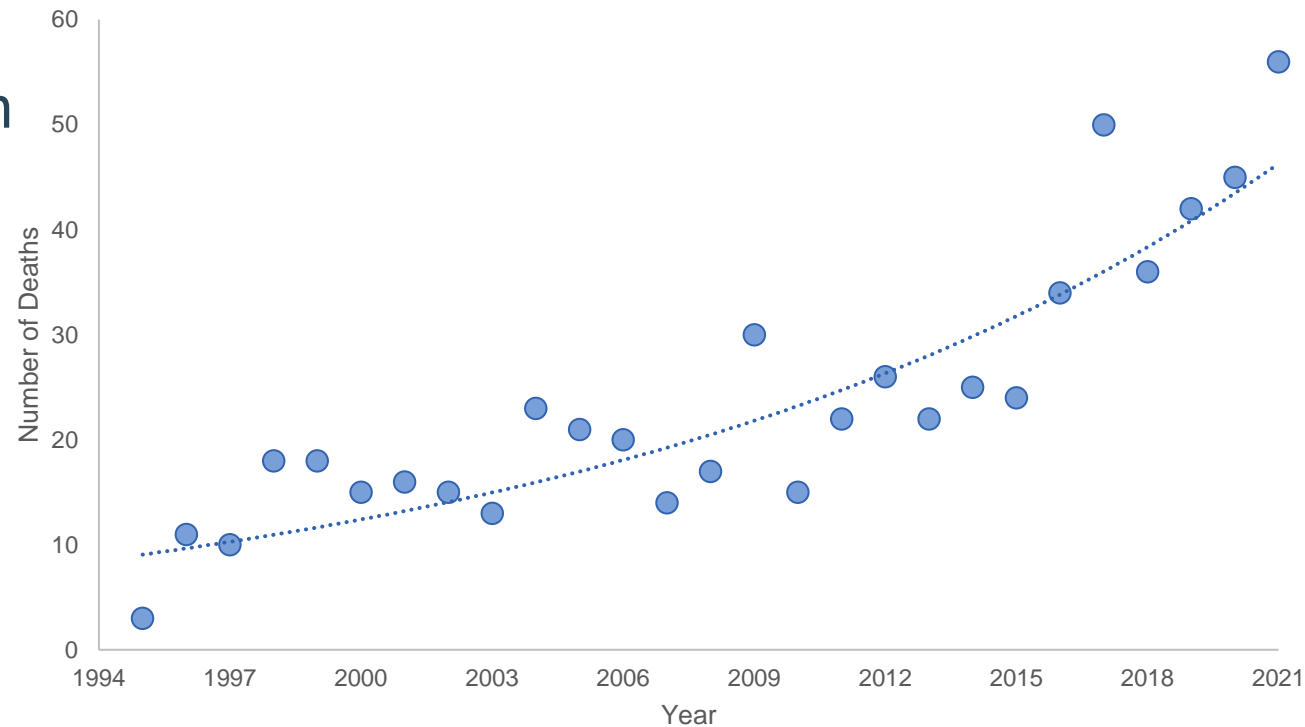
- Tracing, Screening & Matching
 - Geographic Distribution of Deaths



Source: NDI, 1995- 2021

Wave V Vital Events – Results

- Tracing, Screening & Matching
 - Temporal Distribution of Deaths



Wave V Vital Events – Results

- Tracing, Screening & Matching

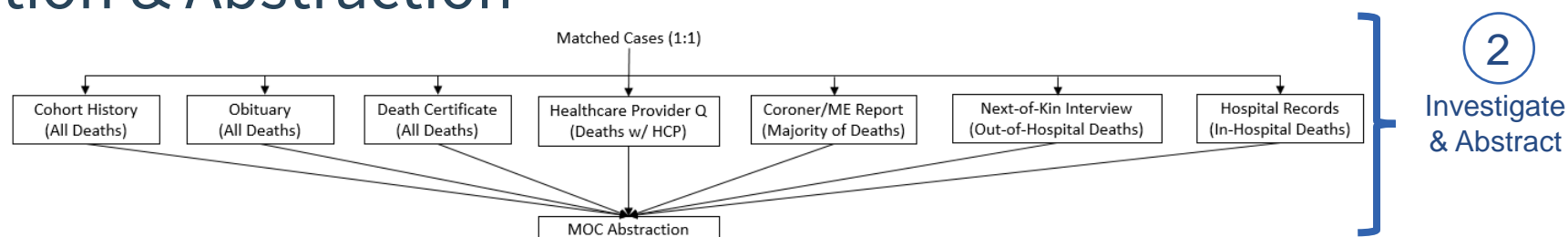
- Demographic Distribution of Deaths

Characteristic		Mean (Range) or %
Age, years		32.3 (14-46)
Female		37%
Race/ethnicity	EA	53%
	AA	25%
	HL	12%
	A/PI	5%
	AI/AN	3%
	O/M	2%

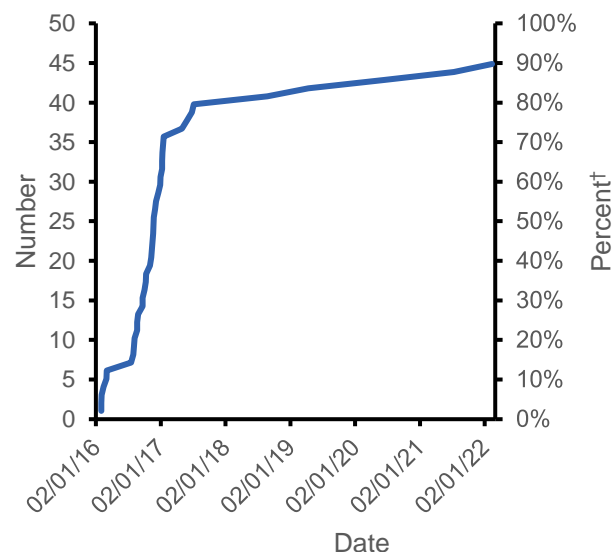
AA = African American. AI/AN = American Indian/Alaskan Native.
A/PI = Asian/Pacific Islander. EA = European American.
HL = Hispanic/Latino. O/M = Other/Multiple.

Wave V Vital Events – Results

- Investigation & Abstraction



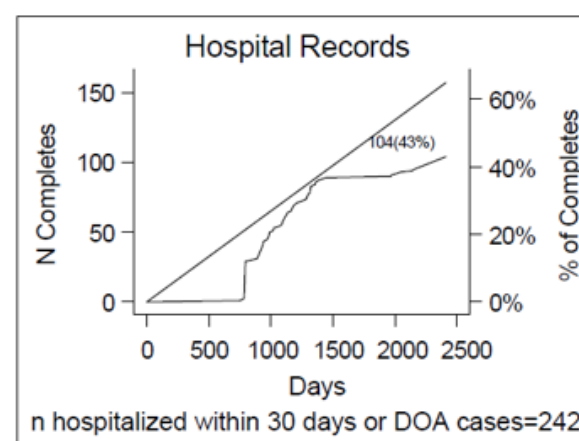
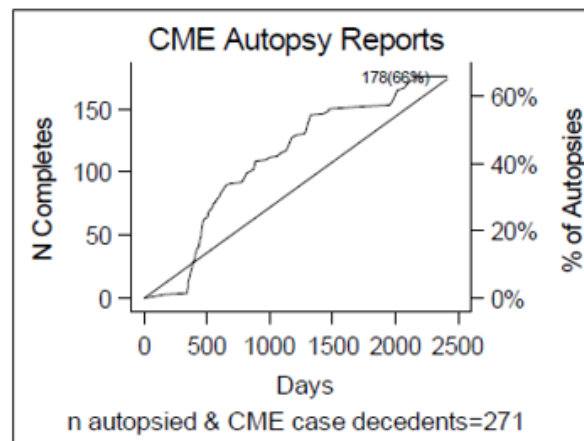
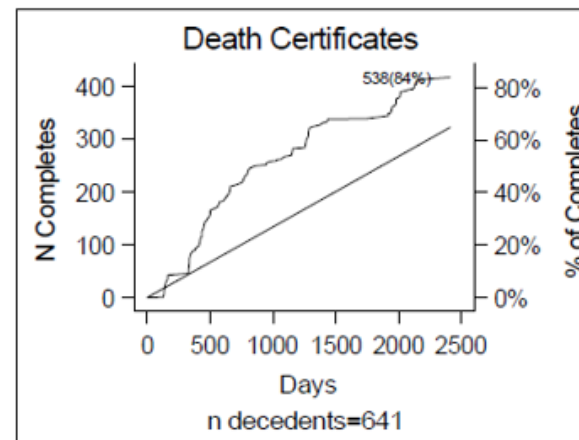
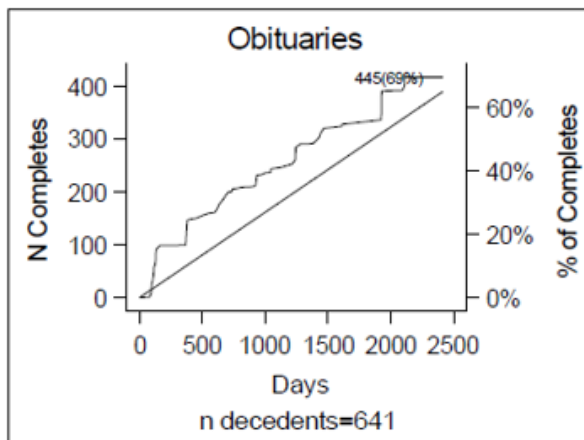
Executed Add Health-State* Agreements
to Provide Death Certificates



*Includes U.S. states, U.S. Army, U.S. Marines & Mexico. †Denominator = states with an Add Health decedent.

Wave V Vital Events – Results

- Investigation & Abstraction
 - Abstracted Records



Wave V Vital Events – Results

- Investigation & Abstraction
 - Quality Control

Abstraction Form	Agreement	Kappa
Obituary	0.86 (0.84-0.89)	0.83 (0.80-0.86)
Death Certificate	0.93 (0.92-0.95)	0.92 (0.90-0.94)
CME Autopsy Report	0.90 (0.87-0.93)	0.86 (0.83-0.90)
Hospital Record*	0.94 (0.92-0.95)	0.91 (0.89-0.93)

Among a random sample of 28 decedents and an oversample of 28 hospitalized decedents enriched 3:1 for cardiovascular disease. CME = Coroner / Medical Examiner. Kappa = prevalence- and bias-adjusted kappa coefficient. *Mean, biomarker-specific intra-class correlation coefficient (95% confidence interval) = 0.96 (0.95-0.98).

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Wave V Vital Events – Results

- Investigation & Abstraction

- Manner & Underlying Cause of Death

Manner of Death*	%
Accidental	41.6
Natural	33.4
Suicide	13.2
Homicide	10.1
Undetermined	1.6

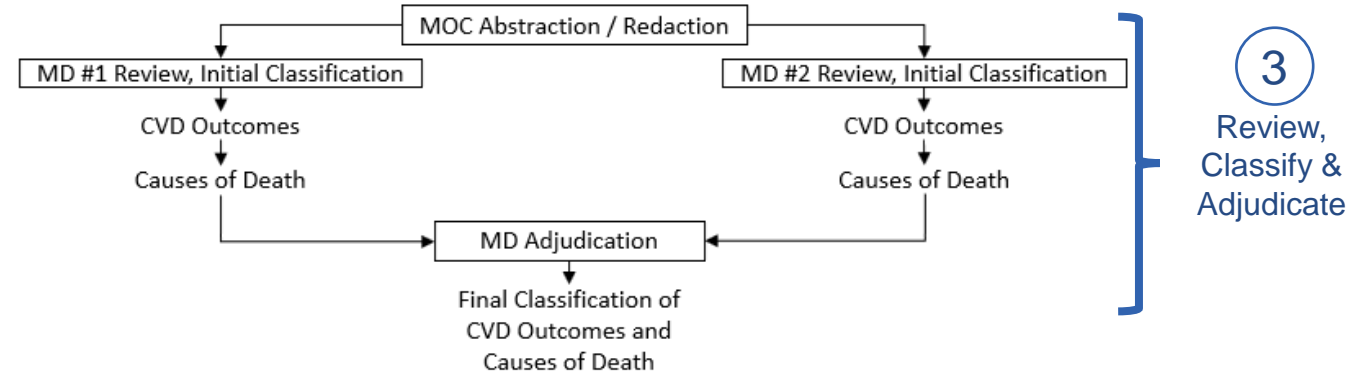
*From death certificate

Underlying Cause of Death†	%
Motor Vehicle Accident	16.1
Cardiovascular Disease	15.1
Accidental Drug Intoxication	13.9
Suicide	11.1
Cancer	9.4
Homicide	7.2
Other Natural Cause	7.0
Infectious Disease	3.7
Other Accident	3.3
Unknown/Undetermined	3.3
Respiratory Disease	2.5
Digestive Disease	2.3
COVID-19	2.2

†From ICD Codes (NDI)

Wave V Vital Events – Results

- Review, Classification & Adjudication



In Progress!

Wave V Biological Data & Vital Events

- Summary
 - Wave V biological data, weights, documentation & biospecimens available
 - sample size ~ 5,400
 - quality high
 - other inflammatory/immune, hepatic & neurodegeneration biomarkers pending
 - Vital events available
 - decedents (1994-2021) = 641
 - cumulative mortality = 3.1%
 - natural causes account for ~ 1/3
 - quality high
 - physician review, classification & adjudication ongoing
 - Stay tuned re dissemination! (<https://addhealth.cpc.unc.edu/documentation/user-guides>)
 - Consider ancillary studies! (<https://addhealth-ancillary.cpc.unc.edu/home>)



Acknowledgements

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Add Health was originally designed by J. Richard Udry, Peter S. Bearman, and Kathleen Mullan Harris at the University of North Carolina at Chapel Hill. Add Health is currently directed by Robert A. Hummer; it was previously directed by Kathleen Mullan Harris (2004-2021) and J. Richard Udry (1994-2004).

Information on obtaining Add Health data is available on the project website (<https://addhealth.cpc.unc.edu>).