Add Health
Biology & Birth Records Projects

Add Health User Conference
National Institutes of Health
July 23-24, 2018

Wave V Project PIs: Nancy Dole, PhD, MSPH
Jon Hussey, PhD, MPH
Eric Whitsel, MD, MPH

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The National Longitudinal Study of Adolescent to Adult Health

Wave V Biology Project

- Types of measures
- Measures & classification
- Field operations
- Results
- Quality control
- Birth records
- Surveillance of chronic disease events

Add Health Choice of Biological Data

- Biological states prevalent in the general young adult population
- Biological states and processes linked to future health
- Measures that can characterize those processes
- Feasible for a large, national, longitudinal field study
- Valid and reliable

TYPES OF MEASURES

Add Health Biological Content Across Waves I–V

Domains	Waves I, II (ages 12–20)	Wave III (ages 18–26)	Wave IV (ages 24–32)	Wave V (ages 32–40)
Anthropometric	✓	✓	✓	✓
Omic	✓	✓	✓	✓
Infectious		✓		
Cardiovascular			✓	✓
Inflammatory/Immune			✓	✓
Metabolic			✓	✓
Neurocognitive			✓	✓
Pharmacoepidemiologic			✓	✓
Renal				✓

MEASURES & CLASSIFICATIONS

Wave V Biomarkers that Approximate Clinical Values

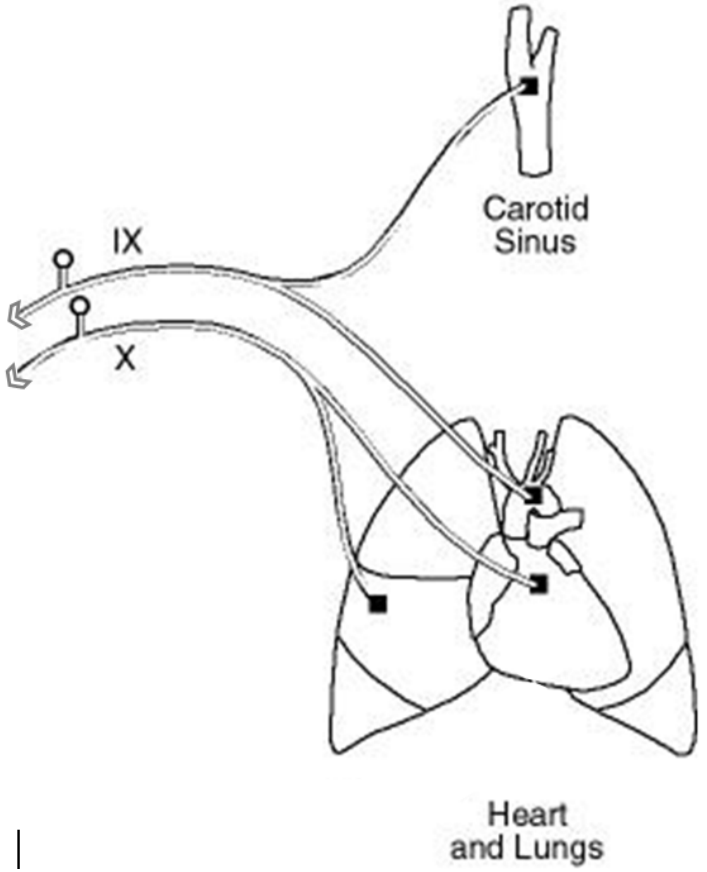
Domains	Measures
REPEAT MEASURES ACROSS WAVES	
Cardiovascular	systolic BP, diastolic BP, pulse rate
Anthropometric	weight, height, arm & waist circumference
Metabolic	HbA_{1c} , glucose, lipid panel
Inflammatory	high-sensitivity C-reactive protein (hsCRP)
Pharmacologic	prescription medication use & classification
NEW MEASURES	
Kidney function	creatinine, cystatin C

Results returned to respondents: HbA_{1c} , glucose, lipid panel, creatinine

Wave V Biomarkers – Measures

Cardiovascular

- Primary
  - systolic blood pressure (SBP)
  - diastolic blood pressure (DBP)
  - pulse rate (PR)



Wave V Biomarkers – Measures

Cardiovascular

SBP/DBP classified 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

*Whelton PK, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults. *Hypertension* 2018;71:1269-1324.

Wave V Biomarkers – Measures

Anthropometric

- Primary
  - weight
  - height
  - waist circumference
- Secondary
  - body mass index (BMI = weight in kg / height in m^2)

Wave V Biomarkers – Measures

Anthropometric (Classified according to NHLBI Evidence Report*)

- **BMI**
  - < 18.5 kg/m^2 — Underweight
  - 18.5-24.9 kg/m^2 — Normal
  - 25.0-29.9 kg/m^2 — Overweight
  - 30.0-34.9 kg/m^2 — Obesity, Stage I
  - 35.0-39.9 kg/m^2 — Obesity, Stage II
  - ≥ 40.0 kg/m^2 — Obesity, Stage III
- **Waist**
  - ≤ 88 cm in ♀, ≤ 102 cm in ♂ — Lower Risk
  - > 88 cm in ♀, > 102 cm in ♂ — High Risk

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*Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults – the evidence report. *Obesity Res* 1998;6(S2);51S-210S.

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Wave V Biomarkers – Measures

Metabolic, lipids

- Primary
  - total cholesterol (TC)
  - high density lipoprotein cholesterol (HDL-C)
  - triglycerides (TG)

Wave V Biomarkers – Measures

Metabolic, lipids (Classified 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

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*Third Report of the National Cholesterol Education Program (NCEP) on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III).
†Spuriously high in the non-fasting state.

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Wave V Biomarkers – Measures

Metabolic, glucose homeostasis

- Primary
  - glycosylated hemoglobin (HbA_{1c})
  - glucose

Wave V Biomarkers – Measures

Metabolic, glucose homeostasis

- Classified according to Am Diabetes Assn guidelines*
  - *fasting glucose*

≤ 99 mg/dl	normal
100-125 mg/dl	impaired
≥ 126 mg/dl	diabetes

  - *random glucose*

≥ 200 mg/dl	diabetes

  - Hb_{A1c}

5.7-6.4%	increased risk for diabetes
≥ 6.5%	diabetes

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*American Diabetes Association. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018. *Diabetes Care* 2018;41(S1): S13-S27.

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Wave V Biomarkers – Measures

Immune / Inflammatory

- high sensitivity C-reactive protein (hsCRP)
  - classified according to CDC / AHA guidelines*
    - low < 1 mg/L
    - average 1-3 mg/L
    - high > 3 mg/L
  - values > 10 mg/L trigger search for factors capable of confounding hsCRP-based CVD risk estimates

*Pearson et al. Markers of inflammation and cardiovascular disease. Application to clinical and public health practice. A statement for healthcare professionals from the CDC and AHA. *Circulation* 2003;107:499-511.

Wave V Biomarkers – Measures

Pharmacologic

- prescription medications
- select over-the-counter medications (salicylates/NSAIDS)
- therapeutically classifications (Multum Lexicon Plus®)
- classification examples
  - antihypertensives
  - antihyperlipidemics
  - antidepressants
  - other classes

FIELD OPERATIONS

The Home Visit at a Glance

Most visits Monday – Friday mornings

Visit lasts 30 – 60 minutes

Staff use Add Health-provided equipment

Visit guided by Samsung tablet

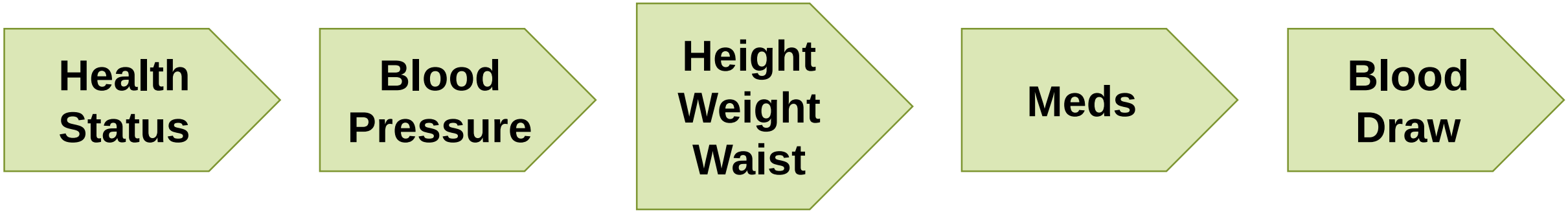
Scheduling In-Home Visits

- Visits are scheduled by examiner
  - Monday – Friday morning or early afternoon
  - Evening or Sundays (as a last resort)

  - No Thursday or Friday evening / Saturday visits
    → Lab is closed on Sundays

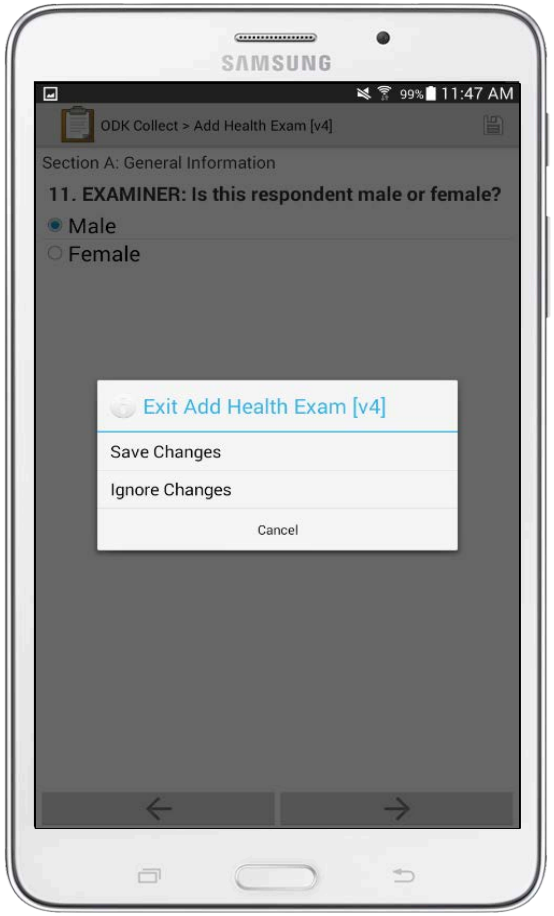
	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	✓	✓★	✓★	✓★	✓★	✓★	✗
Afternoon	✓	✓★	✓★	✓★	✓	✓	✗
Evening	✓	✓	✓	✓	✗	✗	✗

Steps of the In-Home Visit



Tablet Data Collection for Wave V Bio-visit

- Standardized instrument
  - Guides the visit
  - Collects factors that affect measures
  - Built-in skips and sub-study evaluation
  - Medication inventory
  - Guides blood processing and shipping
  - Increased data quality
  - Rapid receipt of the data



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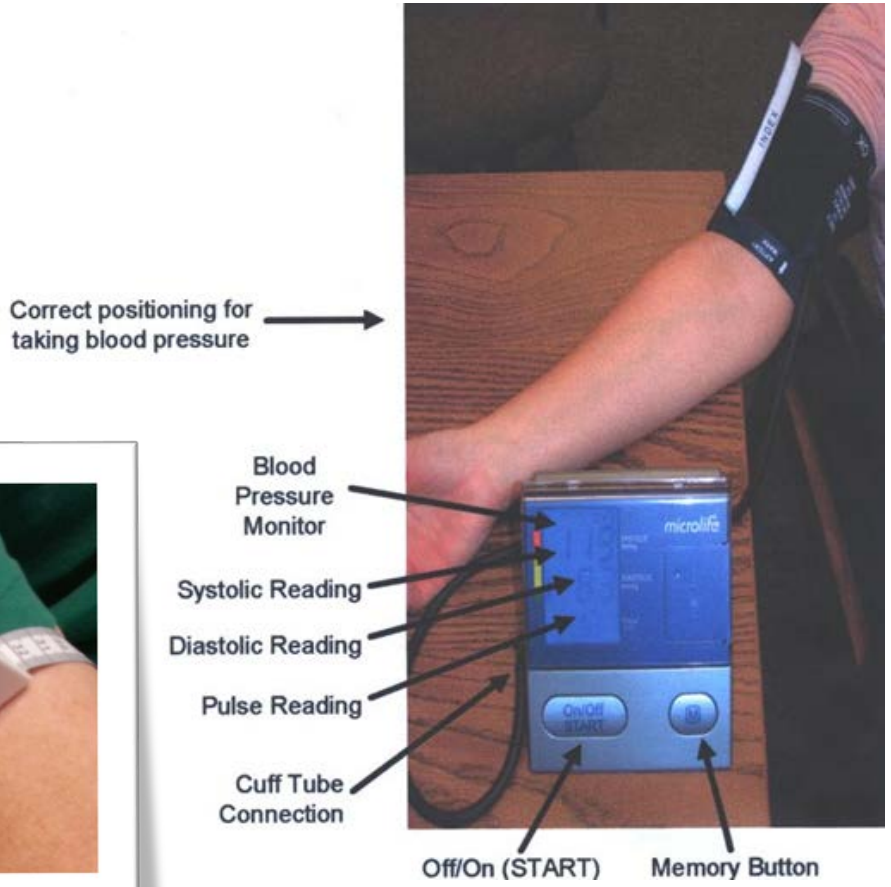
Wave V Biomarkers
Cardiovascular Data Collection Protocol

- Resting & seated respondents
- Measure arm circumference, match cuff
- Systolic BP, diastolic BP & pulse rate
- Measure 3 times @ 30-sec intervals
- Average last 2 measures



*Whelton PK, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults. *Hypertension* 2018;71:1269-1324.

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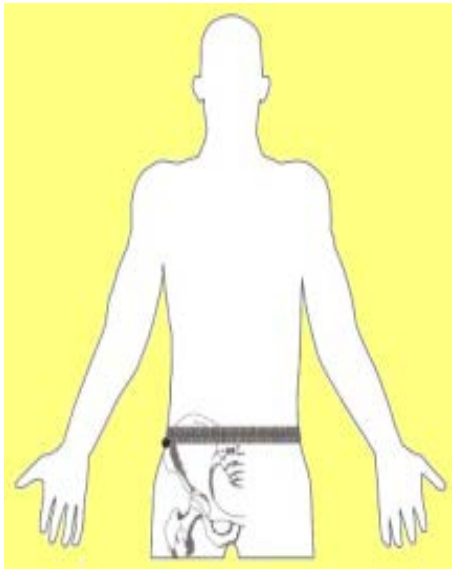
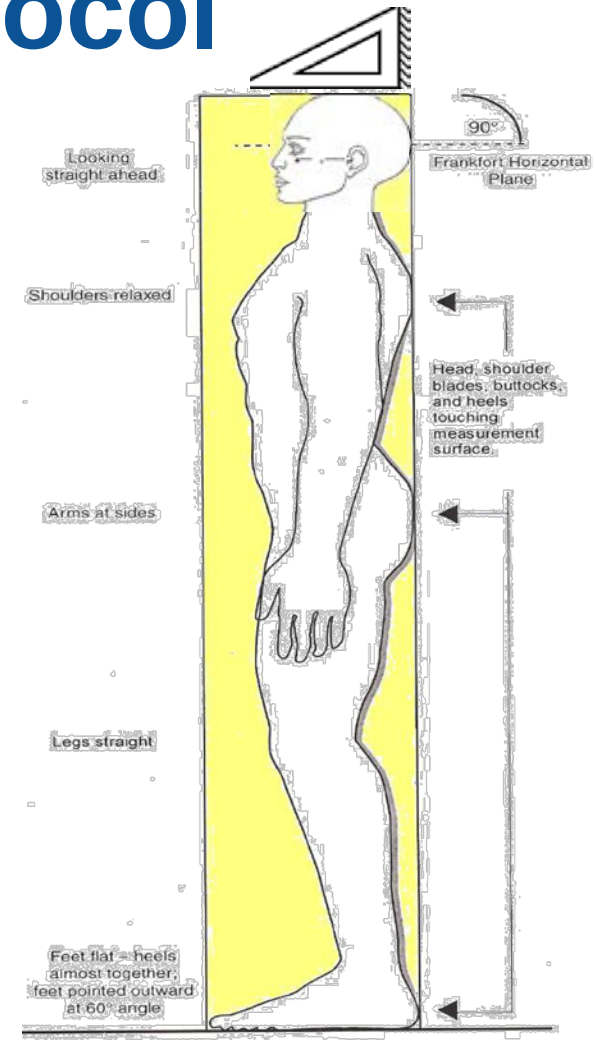
Wave V Biomarkers
Anthropometric Data Collection Protocol

- Respondent dressed, no shoes
- Scale placed on uncarpeted floor
- Standardized study equipment
- Measure Height, Weight, Waist





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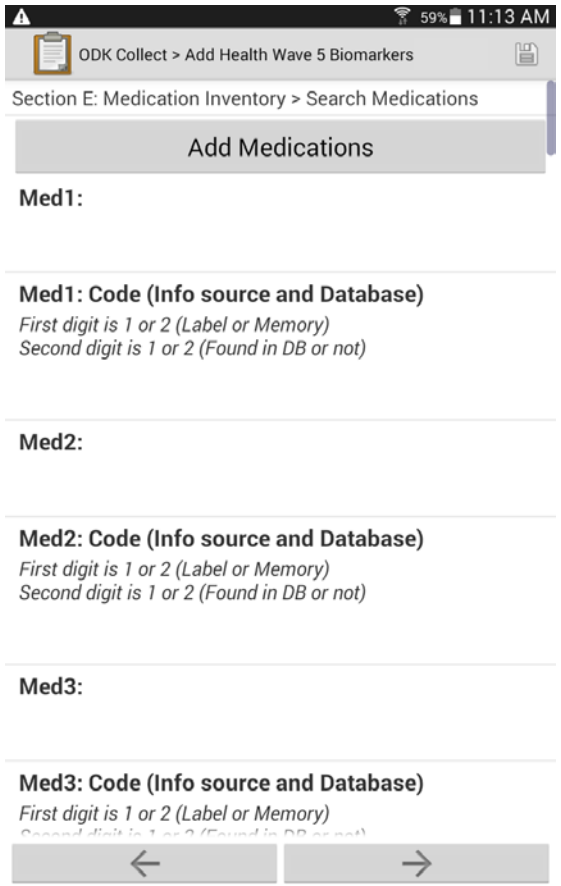
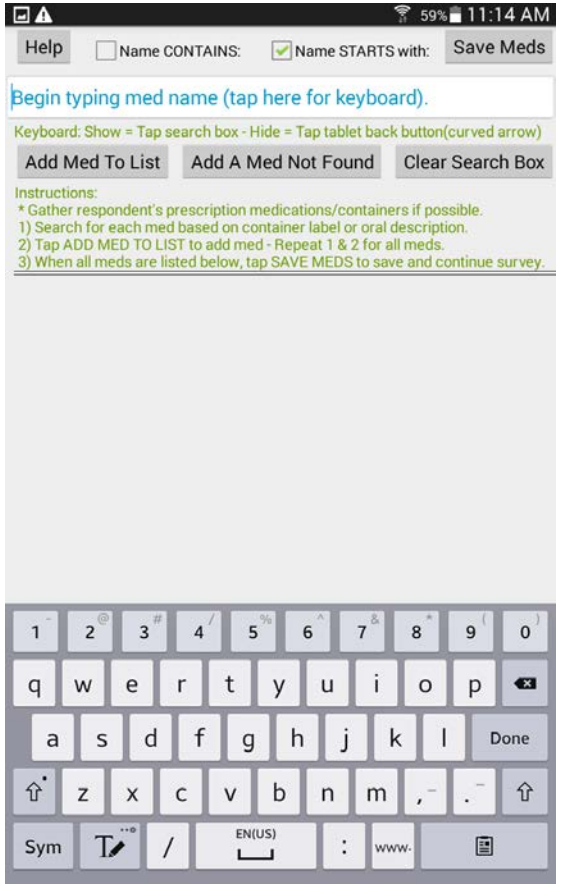
Medication Inventory

Initial Screen



Entering Medication



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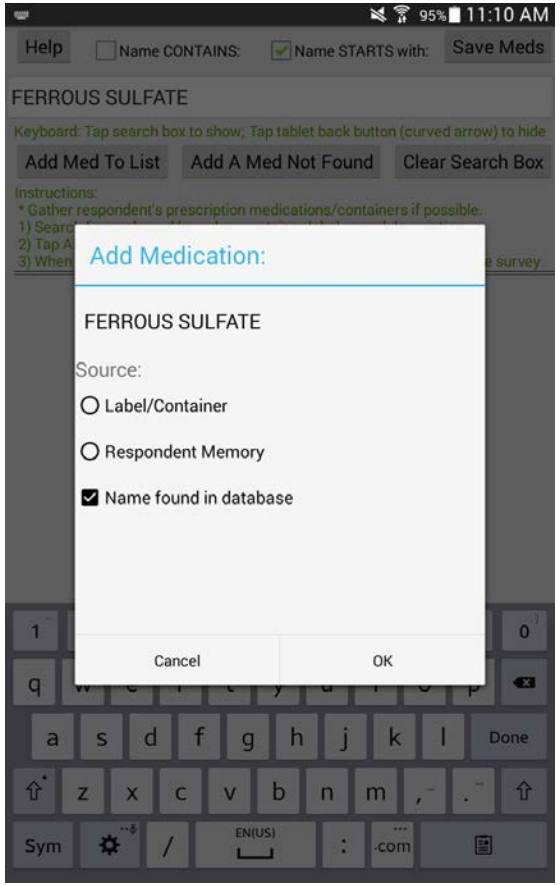

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Exam Blood Kit Contents

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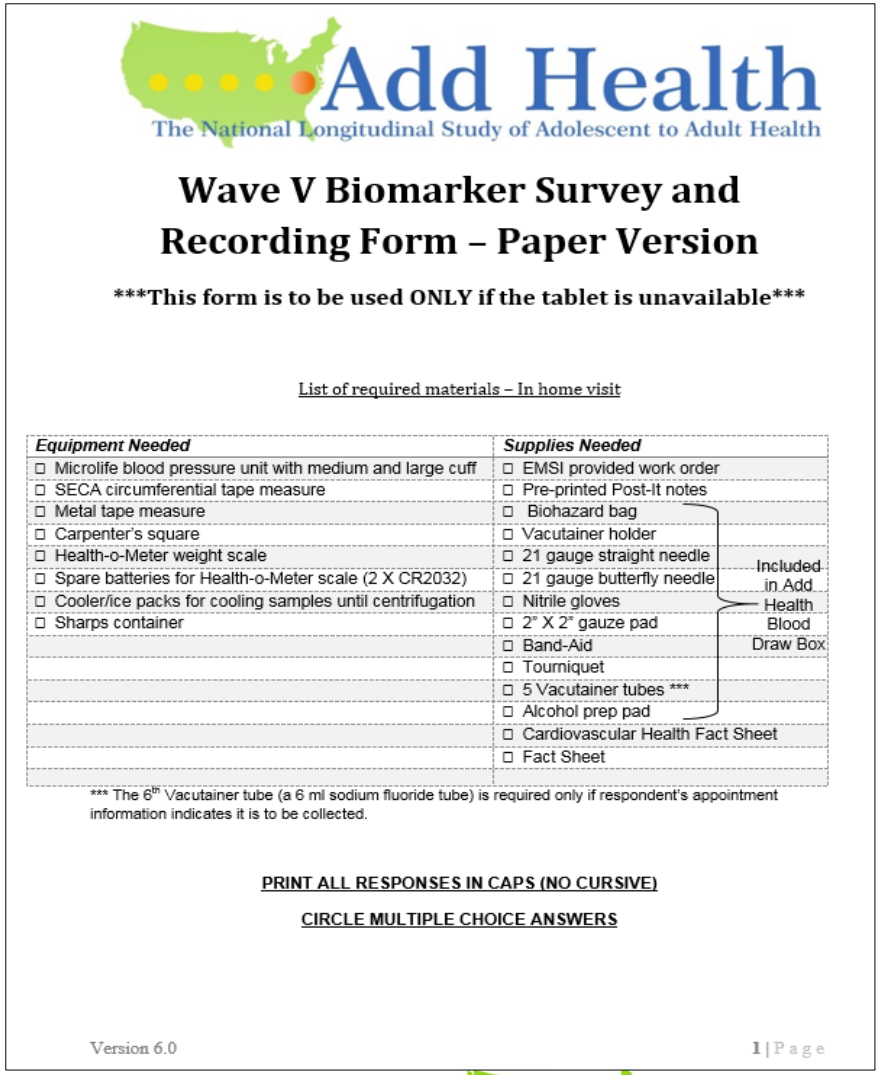
Venous Whole Blood Collection

- Phlebotomists
- Fasting respondents (ideally)
- 5 or 6 vacutainer tubes collected
- Centrifuge as appropriate
- Package & ship to lab
- Provide most assay results to respondents who want them

Paper Version of Questionnaire

- Used only if tablet unavailable
- All calculations performed by hand
- Data must be transferred to tablet and uploaded within 24 hours.
- Follow all skip patterns carefully



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Wave V Biomarker Survey and Recording Form – Paper Version

*****This form is to be used ONLY if the tablet is unavailable*****

List of required materials – In home visit

Equipment Needed	*Supplies Needed*	
☐ Microlife blood pressure unit with medium and large cuff	☐ EMSI provided work order	
☐ SECA circumferential tape measure	☐ Pre-printed Post-It notes	
☐ Metal tape measure	☐ Biohazard bag	Included in Add Health Blood Draw Box
☐ Carpenter's square	☐ Vacutainer holder	
☐ Health-o-Meter weight scale	☐ 21 gauge straight needle	
☐ Spare batteries for Health-o-Meter scale (2 X CR2032)	☐ 21 gauge butterfly needle	
☐ Cooler/ice packs for cooling samples until centrifugation	☐ Nitrile gloves	
☐ Sharps container	☐ 2" X 2" gauze pad	
	☐ Band-Aid	
	☐ Tourniquet	
	☐ 5 Vacutainer tubes ***	
	☐ Alcohol prep pad	
	☐ Cardiovascular Health Fact Sheet	
	☐ Fact Sheet	

*** The 6th Vacutainer tube (a 6 ml sodium fluoride tube) is required only if respondent's appointment information indicates it is to be collected.

PRINT ALL RESPONSES IN CAPS (NO CURSIVE)

CIRCLE MULTIPLE CHOICE ANSWERS

Version 6.0 1 | Page

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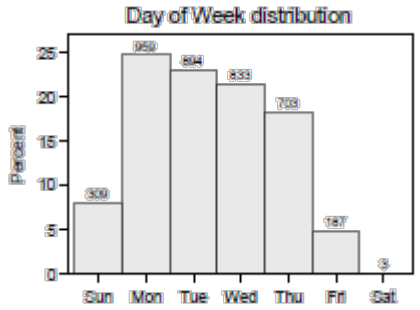
Where Are We Today with Bio-Visits?

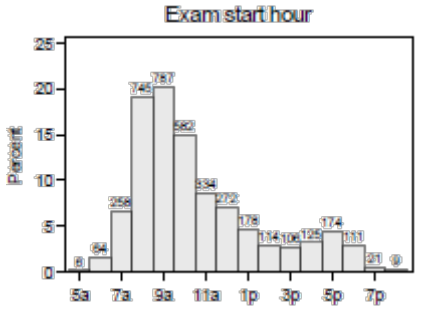
- 7,605 respondents consented
- 3,755 (49% of) home visits completed

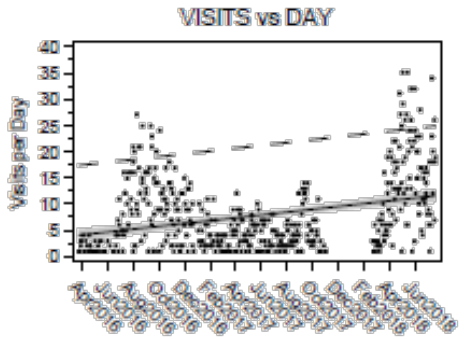
Results

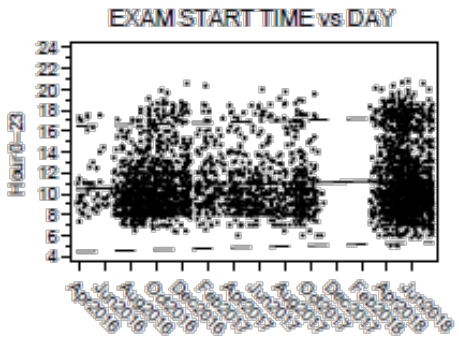
ADD HEALTH WAVE V (2016–2018)
3. SUMMARY STATISTICS
NUMBER, DURATION & TIME OF VISITS

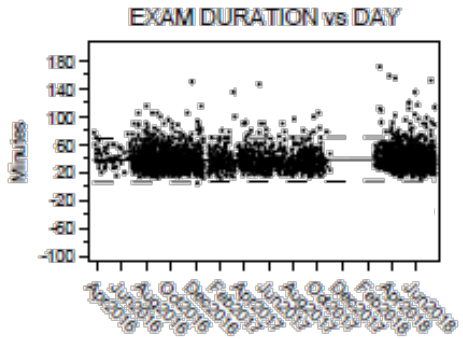
	MEAN	SD	CV	P1	P5	P10	P25	P50	P75	P90	P95	P99
Exam Visits per Day	7.8	7.1	90.4	1.0	1.0	1.0	2.0	6.0	12.0	18.0	23.0	32.0
Exam Start Time (hour 0–23)	10.9	3.1	28.0	6.6	7.5	8.0	8.8	10.0	12.3	16.3	17.6	18.8
Exam Duration (min)	38.3	15.5	40.3	15.3	20.0	23.0	28.9	35.3	45.0	57.0	65.0	90.0











X axes = Exam date (3/24/2016–7/18/2018)
95% Confidence Limits – – – 95% Prediction Limits —— Regression
3,888 exams of 3,755 individuals on 496 exam days (3/24/2016–7/18/2018).

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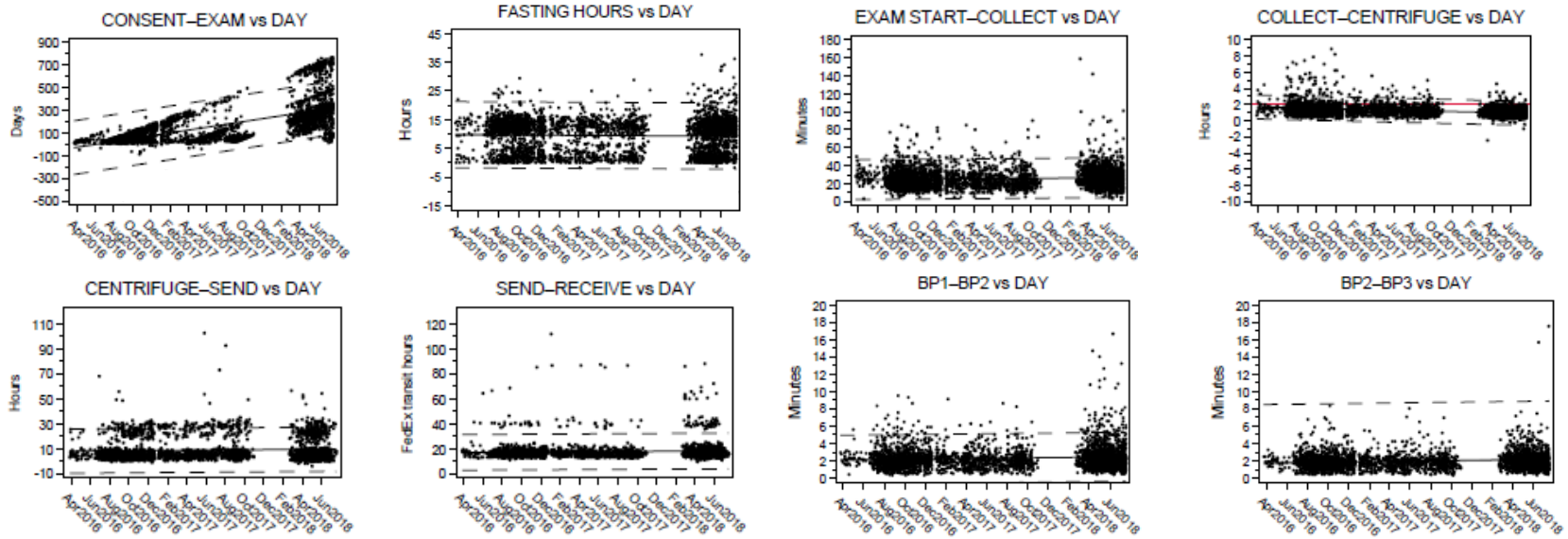
The National Longitudinal Study of Adolescent to Adult Health

Results

ADD HEALTH WAVE V (2016–2018)
3. SUMMARY STATISTICS
INTERVALS

	MEAN	SD	CV	P1	P5	P10	P25	P50	P75	P90	P95	P99
Interval (day): consent-exam	175.6	162.6	92.6	11.0	20.0	25.0	46.0	128.0	263.0	342.0	531.0	719.0
Fasting Hours	9.4	5.9	62.1	0.0	0.5	1.1	3.4	11.2	13.5	15.4	16.8	24.0
Interval (min): BP1–BP2	2.3	1.4	62.3	0.5	0.9	1.1	1.5	2.1	2.7	3.7	4.7	7.2
Interval (min): BP2–BP3	2.0	3.4	170.3	0.5	0.8	1.0	1.4	1.8	2.3	2.9	3.5	5.3
Interval (min): exam start–collect	25.5	10.8	42.4	9.0	12.7	15.0	19.0	24.0	30.0	38.0	43.5	62.0
Interval (hr): collect–centrifuge	1.2	0.8	65.3	0.3	0.4	0.6	0.8	1.1	1.6	2.0	2.3	4.4
Interval (hr): centrifuge–send	8.9	9.0	101.4	0.3	1.0	1.8	3.5	5.8	8.7	24.2	28.2	32.7
Interval (hr): send–receive	17.5	7.1	40.4	12.5	13.3	13.7	14.8	16.1	17.7	20.4	23.1	44.4



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95% Confidence Limits – – – 95% Prediction Limits —— Regression
3,888 exams of 3,755 individuals on 496 exam days (3/24/2016–7/18/2018).

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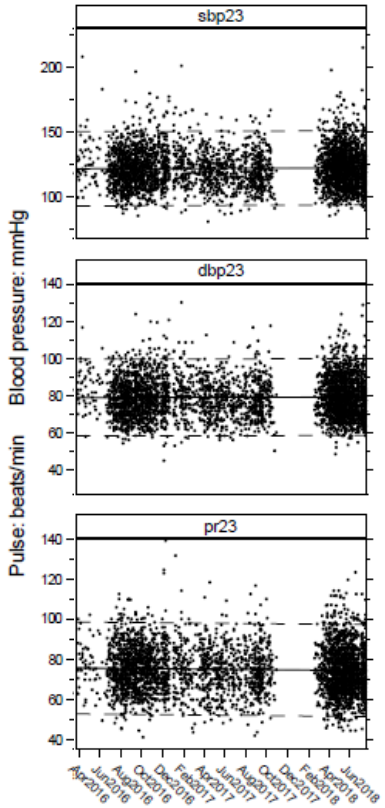
Results

ADD HEALTH WAVE V (2016–2018)
3. SUMMARY STATISTICS
CARDIOVASCULAR MEASURES

	MEAN	SD	CV	P1	P5	P10	P25	P50	P75	P90	P95	P99
SBP23 (mm Hg)	122	15	12	94	101	105	112	121	131	140	147	165
DBP23 (mm Hg)	79	11	13	59	64	66	72	79	86	93	97	107
PR23 (bpm)	75	12	16	50	57	61	67	74	82	90	95	106



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▫ 95% Confidence Limits – – – 95% Prediction Limits —— Regression
3,888 exams of 3,755 individuals on 496 exam days (3/24/2016–7/18/2018).

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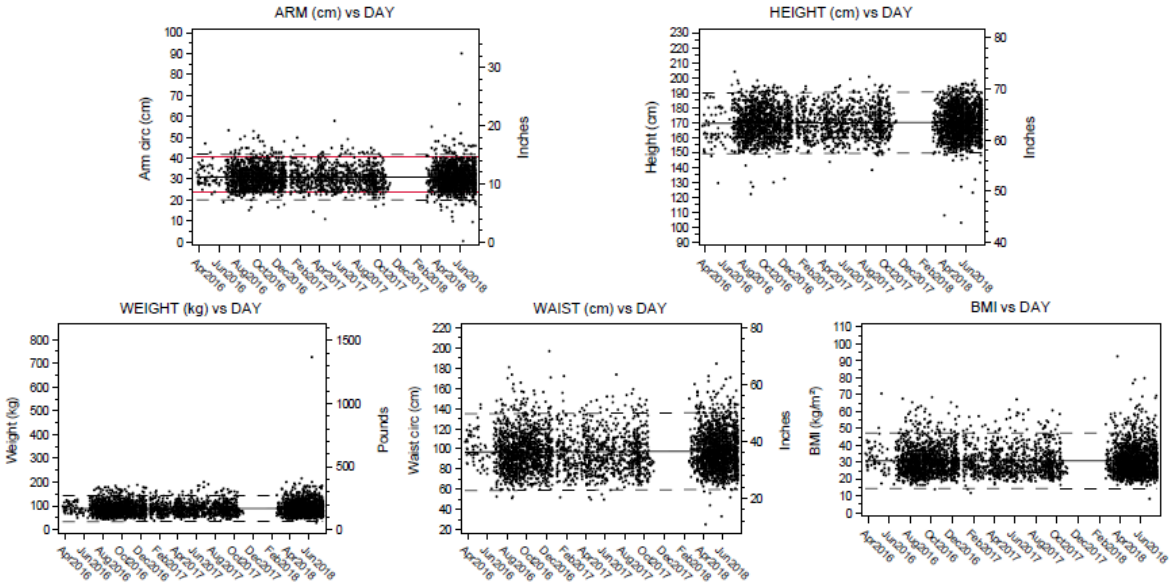
Results

ADD HEALTH WAVE V (2016–2018)
3. SUMMARY STATISTICS
ANTHROPOMETRIC MEASURES

	MEAN	SD	CV	P1	P5	P10	P25	P50	P75	P90	P95	P99
Arm (cm)	30.8	5.3	17.2	21.0	24.0	24.5	27.0	30.5	34.0	37.5	39.5	45.0
Height (cm)	169.6	11.0	6.5	149.0	154.5	157.0	162.0	169.5	177.0	183.0	187.0	193.0
Weight (kg)	89.1	27.7	31.1	47.0	55.7	60.0	70.5	85.4	102.0	123.0	137.0	173.5
Waist (cm)	97.1	19.0	19.6	63.0	70.0	75.0	84.0	95.0	108.0	123.0	132.0	152.0
BMI (kg/m²)	31.2	12.6	40.6	18.4	20.5	22.0	24.8	29.2	34.9	41.7	47.3	59.8



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95% Confidence Limits – – – 95% Prediction Limits —— Regression
3,888 exams of 3,755 individuals on 496 exam days (3/24/2016–7/18/2018).

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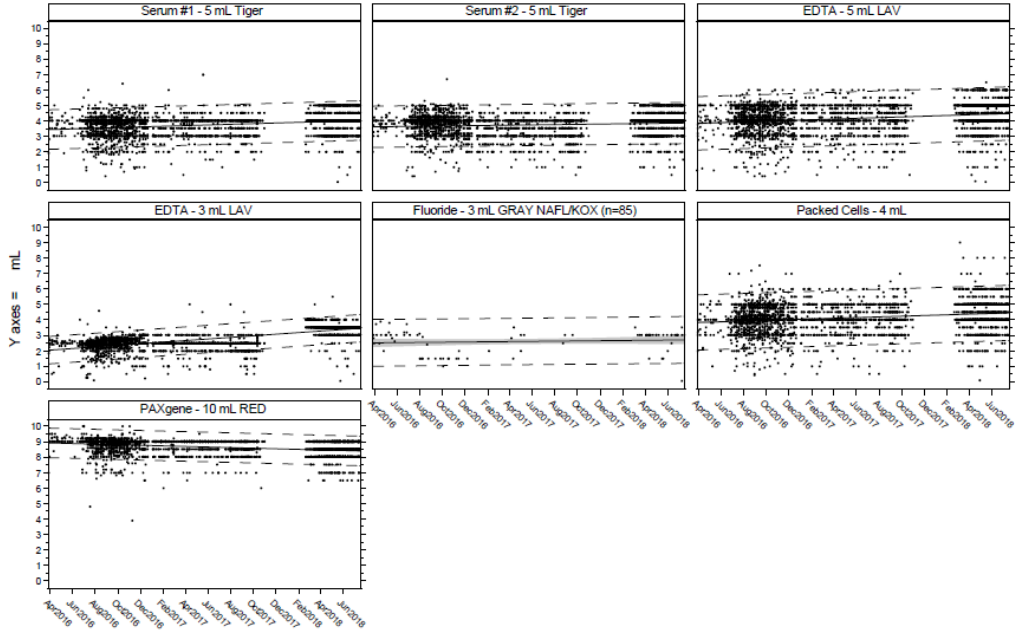
Results

ADD HEALTH WAVE V (2016–2018)
3. SUMMARY STATISTICS
SHIPPED BLOOD VOLUMES

	MEAN	SD	CV	P1	P5	P10	P25	P50	P75	P90	P95	P99
Sample volume (mL): 5 TIGER1	3.8	0.7	18.0	1.8	2.6	3.0	3.5	4.0	4.0	4.5	5.0	5.0
Sample volume (mL): 5 TIGER2	3.8	0.7	18.3	1.5	2.5	3.0	3.5	4.0	4.0	4.5	4.9	5.0
Sample volume (mL): 5 LAV KEDTA	4.2	0.9	21.5	1.0	2.7	3.0	4.0	4.1	5.0	5.0	5.2	6.0
Sample volume (mL): 3 LAV KEDTA	2.9	0.6	22.6	1.0	2.0	2.0	2.5	2.8	3.5	3.5	3.5	4.0
Sample volume (mL): 4 PACKED CELLS	4.2	0.9	22.3	1.5	2.8	3.0	3.9	4.0	5.0	5.0	5.5	6.0
Sample volume (mL): 10 RED PAXGENE	8.6	0.5	6.0	7.0	8.0	8.0	8.3	8.9	9.0	9.0	9.1	9.3



X axes = Exam date (3/24/2016–7/18/2018)
95% Confidence Limits – – – 95% Prediction Limits —— Regression
3,617 blood sample kits from 435 FedEx delivery days (3/29/2016–7/17/2018).

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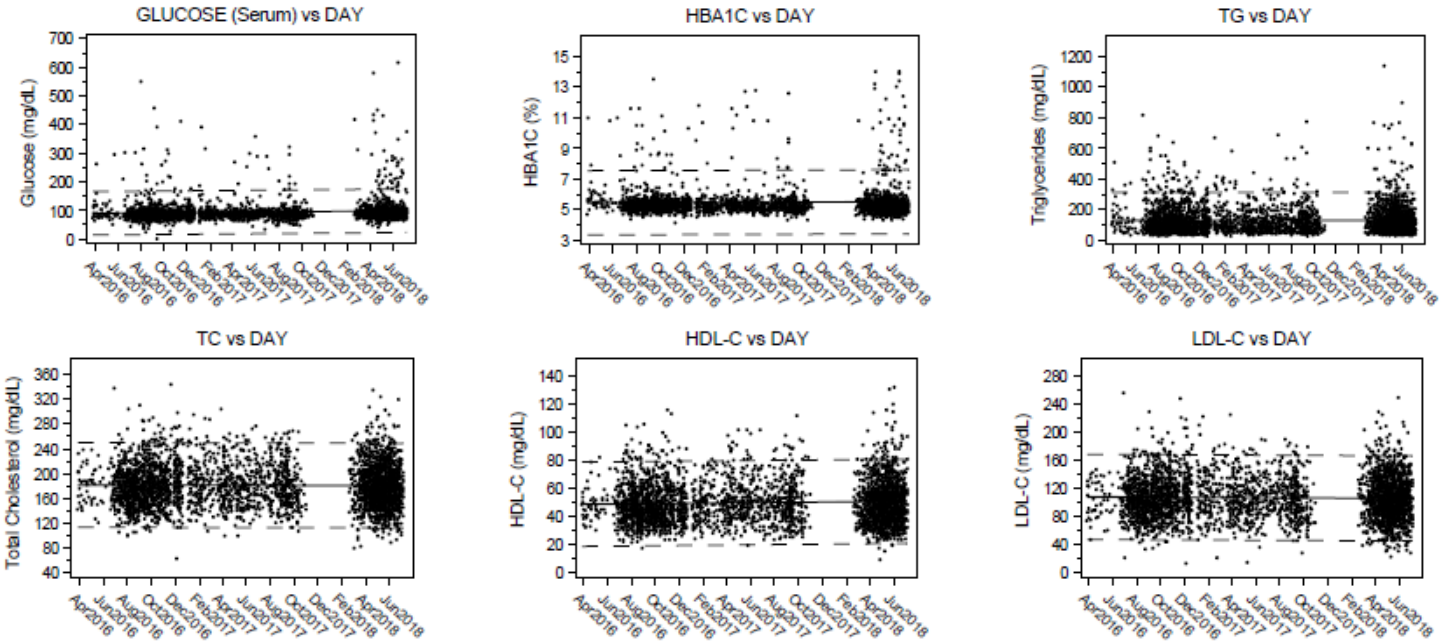
Results

ADD HEALTH WAVE V (2016–2018)
3. SUMMARY STATISTICS
METABOLIC MEASURES

	MEAN	SD	CV	P1	P5	P10	P25	P50	P75	P90	P95	P99
GLUCOSE (SERUM) (mg/dL)	93.9	36.5	38.9	55.0	69.0	74.0	81.0	88.0	96.0	108.0	129.0	279.0
HBA1C (%)	5.4	0.9	16.6	4.6	4.8	4.9	5.0	5.2	5.5	5.7	6.2	10.6
TG (mg/dL)	127.4	92.2	72.3	35.0	45.0	52.0	70.0	101.0	154.0	233.0	291.0	507.0
TC (mg/dL)	180.5	34.6	19.2	110.0	130.0	140.0	156.0	177.0	202.0	226.0	242.0	274.0
HDL-C (mg/dL)	49.5	15.0	30.2	24.0	29.0	33.0	39.0	47.0	58.0	70.0	77.0	94.0
LDL-C (mg/dL)	106.2	30.6	28.8	44.0	60.0	69.0	85.0	104.0	125.0	145.0	159.0	189.0



X axes = Exam date (3/24/2016–7/18/2018)
▫ *95% Confidence Limits* – – – *95% Prediction Limits* —— *Regression*
Weekly assays through 7/6/2018 from 3,479 kits.
HBA1C assays through 7/10/2018 from 3,479 kits.

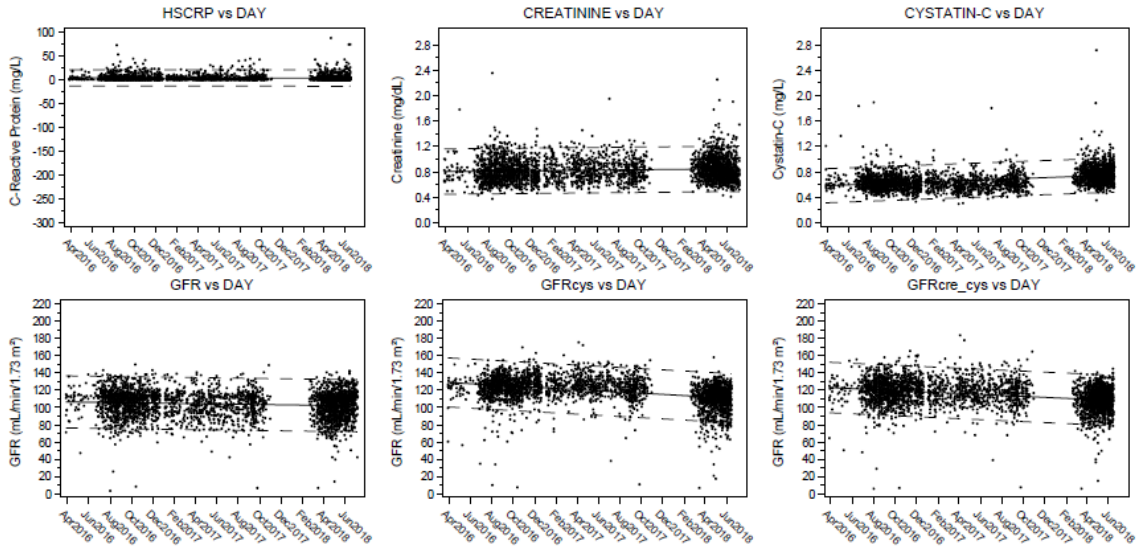
UNC CAROLINA POPULATION CENTER

Add Health
The National Longitudinal Study of Adolescent to Adult Health

Results

ADD HEALTH WAVE V (2016–2018)
3. SUMMARY STATISTICS
INFLAMMATORY/RENAL MEASURES

	MEAN	SD	CV	P1	P5	P10	P25	P50	P75	P90	P95	P99
HSCRP (mg/dL)	3.9	8.9	229.9	0.2	0.2	0.4	0.7	1.7	4.5	9.6	15.9	29.0
CREATININE (mg/dL)	0.8	0.4	42.4	0.5	0.6	0.6	0.7	0.8	0.9	1.1	1.1	1.3
CYSTATIN-C (mg/L)	0.7	0.2	33.9	0.4	0.5	0.5	0.6	0.7	0.8	0.9	0.9	1.1
GFR (mL/min/1.73 m²)	103.8	15.4	14.8	65.4	77.4	83.7	94.2	106.2	113.7	120.8	127.6	136.3
GFR_{cys}	118.6	15.7	13.2	68.5	90.1	100.6	111.5	120.2	128.1	135.1	140.1	149.3
GFR_{cre_cys}	114.5	15.7	13.7	74.7	89.7	95.7	105.5	115.4	124.3	132.6	137.8	149.1



X axes = Exam date (3/24/2016–7/18/2018)
▫ 95% Confidence Limits – – – 95% Prediction Limits —— Regression
Monthly assays through 6/22/2018 from 3,311 kits (HSCRP & CYSTATIN-C).
Weekly assays through 7/6/2018 from 3,479 kits (CREATININE).

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Add Health
The National Longitudinal Study of Adolescent to Adult Health

Quality Control

Threats to Data Quality

- 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

Quality Control

Control of Data Quality

- Uniformly train & monitor staff
- Follow standardized protocol
- Use standard, tested equipment
- Automate processes / checks
- Track / reduce missing data
- Track / reduce measurement error
  - trend / cyclicity
  - digit preference
  - inaccuracy
  - unreliability

Quality Control

Digit Preference

ADD HEALTH WAVE V (2016–2018)
ANTHROPOMETRIC MEASURES

Terminal Digit	ARM (cm)		HEIGHT (cm)		WEIGHT (kg)		WAIST (cm)	
	N	%	N	%	N	%	N	%
0	3189	84%	2879	76%	1079	29%	3250	86%
1					302	8%		
2					242	7%		
3					261	7%		
4					275	7%		
5	624	16%	892	24%	467	13%	535	14%
6					263	7%		
7					279	8%		
8					275	7%		
9					260	7%		
Total:	3813	100%	3771	100%	3703	100%	3785	100%

MEASURE	k	n	ChiSq	p	DPS	FLAG
WAIST (cm)	2	3785	1947.5	0.000	71.7	1
ARM (cm)	2	3813	1725.5	0.000	67.3	1
HEIGHT (cm)	2	3771	1047.0	0.000	52.7	1
WEIGHT (kg)	10	3703	1606.4	0.000	22.0	1

Sorted from high to low DPS. DPS = Hense (1991) digit preference score = 100*(Chisq/(n*(k-1)))0.5. Range = 0–100.*
Chisq = goodness of fit test stat, where n[i] = observed cell freq & sum(n[i]/k) = expected cell freq in cell [i].
k = number of possible digits, i.e. 0 or 5 for terminal digits of arm, height, and waist; 0–9 for all others.
p = p value. Bon Ferroni-corrected alpha = 0.05/13 = 0.00385.

UNC CAROLINA POPULATION CENTER

Add Health
The National Longitudinal Study of Adolescent to Adult Health

Quality Control

Digit Preference

ADD HEALTH WAVE V (2016–2018)

CARDIOVASCULAR MEASURES

Terminal Digit	SBP1 (mm Hg)		SBP2 (mm Hg)		SBP3 (mm Hg)		DBP1 (mm Hg)		DBP2 (mm Hg)		DBP3 (mm Hg)		PR1 (beat/min)		PR2 (beat/min)		PR3 (beat/min)	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
0	418	11%	376	10%	436	12%	469	13%	428	12%	444	12%	427	11%	412	11%	422	11%
1	351	9%	335	9%	331	9%	332	9%	329	9%	323	9%	338	9%	366	10%	354	10%
2	400	11%	404	11%	383	10%	410	11%	423	11%	409	11%	412	11%	380	10%	403	11%
3	363	10%	333	9%	357	10%	409	11%	350	9%	386	10%	360	10%	347	9%	337	9%
4	361	10%	398	11%	389	10%	356	10%	404	11%	360	10%	391	11%	345	9%	426	11%
5	350	9%	366	10%	385	10%	348	9%	334	9%	342	9%	341	9%	392	11%	326	9%
6	372	10%	355	10%	349	9%	333	9%	395	11%	377	10%	387	10%	368	10%	360	10%
7	350	9%	370	10%	340	9%	339	9%	360	10%	333	9%	323	9%	347	9%	369	10%
8	395	11%	425	11%	407	11%	378	10%	358	10%	409	11%	382	10%	389	10%	372	10%
9	360	10%	357	10%	336	9%	346	9%	338	9%	330	9%	359	10%	373	10%	344	9%
Total:	3720	100%	3719	100%	3713	100%	3720	100%	3719	100%	3713	100%	3720	100%	3719	100%	3713	100%

MEASURE	k	n	ChiSq	p	DPS	FLAG
SBP3 (mm Hg)	10	3713	28.7	0.001	2.9	
SBP2 (mm Hg)	10	3719	21.4	0.011	2.5	
SBP1 (mm Hg)	10	3720	13.9	0.125	2.0	
DBP1 (mm Hg)	10	3720	48.3	0.000	3.8	
DBP3 (mm Hg)	10	3713	40.0	0.000	3.5	
DBP2 (mm Hg)	10	3719	33.8	0.000	3.2	
PR3 (beat/min)	10	3713	29.6	0.001	3.0	
PR1 (beat/min)	10	3720	27.3	0.001	2.9	
PR2 (beat/min)	10	3719	11.8	0.225	1.9	

Sorted from high to low DPS. DPS = Hense (1991) digit preference score = 100*(Chisq/(n*(k-1)))0.5. Range = 0–100.*
Chisq = goodness of fit test stat, where n[i] = observed cell freq & sum(n[i]/k) = expected cell freq in cell [i].
k = number of possible digits, i.e. 0 or 5 for terminal digits of arm, height, and waist; 0–9 for all others.
p = p value. Bon Ferroni-corrected alpha = 0.05/13 = 0.00385.

Quality Control

Inaccuracy

Race / Ethnicity	Sex	Glucose Sub-Study*	Cystatin C Sub-Study†
White	Male	12	12
	Female	12	12
Black	Male	12	12
	Female	12	12
Hispanic	Male	12	12
	Female	12	12
Other	Male	12	12
	Female	12	12
Total		96	96

*Involves collecting an extra (NaFl/KOx) tube of blood @ the same exam for a different glucose assay. Includes race/ethnicity-sex strata of 12 participants = 4 normal glucose + 4 pre-diabetes + 4 diabetes.

†Involves measuring cystatin c using a new calibration assay. Includes race/ethnicity-sex strata of 12 participants = 4 + 4 + 4 with cystatin c < 0.6, 0.6-0.7, and > 0.7 mg/L.

Quality Control

Inaccuracy

ADD HEALTH WAVE V (2016–2018)
GLUCOSE SUB-STUDY

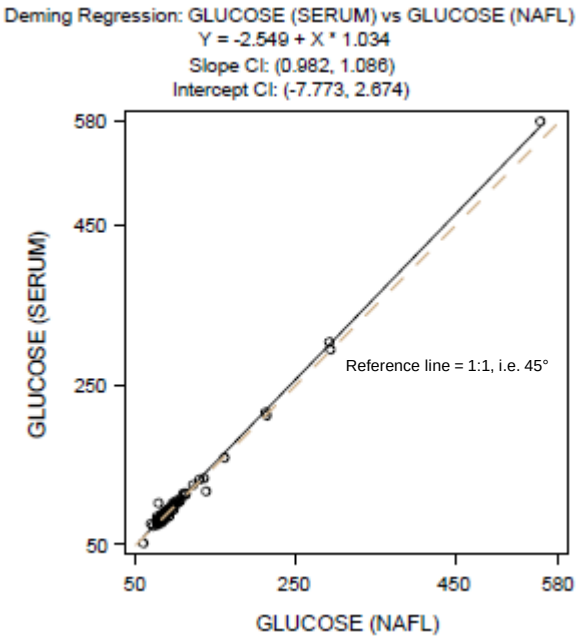
PARTICIPANT CHARACTERISTICS

Characteristic	*N*	*%*
Female	43	62%
Race/Ethnicity: Non-Hispanic White	25	36%
Non-Hispanic Black	14	20%
Hispanic	9	13%
Other	21	30%
Wave IV HBA1C: Normal (<5.7%)	29	42%
Pre-Diabetic (5.7–6.4%)	23	33%
Diabetic (>=6.5%)	17	25%
Pilot Study Participant	21	30%
With both a 5 Gray NAFL/KOX & an 8.5 Tiger	69	100%

BIAS

N	*GLUCOSE (SERUM)*	*GLUCOSE (NAFL)*	*|BIAS|*	*BIAS*	*(95% CI)*	*RB*	*%BIAS~=0*	*P*
69	109.5	108.3	3.5	1.1	(-0.3,2.5)	1.0	100%	0.113

IDENTICAL-AXIS SCATTERPLOT



Cystatin C sub-study is pending

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Add Health
The National Longitudinal Study of Adolescent to Adult Health

Quality Control

Unreliability

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

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

Quality Control

Unreliability

ADD HEALTH WAVE V (2016–2018)
INTRA-INDIVIDUAL VARIATION STUDY

PARTICIPANT CHARACTERISTICS

Characteristic	N	%
FEMALE	54	50%
RACE/ETHNICITY: NON-HISPANIC WHITE	37	35%
NON-HISPANIC BLACK	25	23%
HISPANIC	23	21%
OTHER	22	21%
PILOT STUDY PARTICIPANT	5	5%
WITH BOTH A v1 & v2	107	100%
SAME DAY OF WEEK @ v1 & v2	58	54%
SAME FIELD EXAMINER @ v1 & v2	106	99%
FASTING >= 8 hr @ v1 & v2	83	78%
FASTING >= 9 hr @ v1 & v2	80	75%
ALL ADD HEALTH EQUIPMENT @ v1 & v2	103	96%
ALL PREFERRED UNITS @ v1 & v2	101	94%

BETWEEN-VISIT DIFFERENCES

MEASURE	N	V1	V2	|D|	D	(95% CI)	PE	%D~=0	P
Visit Day (1–366)	107	124.6	137.9	14.0	14.0	(12.96,15.13)	10.7	100%	0.000
Exam Start Time (hour 0–23)	107	9.8	9.6	1.3	-0.1	(-0.52,0.33)	13.1	95%	0.657
Fasting Hours	102	13.2	11.2	3.7	-2.0	(-3.19,-0.88)	30.6	96%	0.001

RELIABILITY

MEASURE	N	ICC	(95% CI)	MDC	MDD	UNIT
SBP23	107	0.72	(0.63,0.81)	21	2	mm Hg
DBP23	107	0.71	(0.62,0.80)	16	2	mm Hg
PR23	107	0.74	(0.65,0.82)	16	2	bpm
Arm	107	0.86	(0.82,0.91)	4.92	0.78	cm
Height	105	0.94	(0.92,0.96)	7.15	1.75	cm
Weight	105	1	(1.00,1.00)	2.84	4.43	kg
Waist	104	0.96	(0.94,0.97)	10.82	3.07	cm
BMI	105	0.98	(0.98,0.99)	2.9	1.3	kg/m²
GLUCOSE	98	0.94	(0.91,0.96)	31	7	mg/dL
HBA1C	96	0.99	(0.99,1.00)	0.3	0.2	%
TG	98	0.63	(0.51,0.75)	172	16	mg/dL
TC	98	0.88	(0.83,0.92)	34	6	mg/dL
HDL-C	98	0.95	(0.93,0.97)	10	3	mg/dL
LDL-C	98	0.86	(0.81,0.91)	30	5	mg/dL
HSCRP	85	0.83	(0.76,0.89)	5.2	0.7	mg/dL
CREATININE	98	0.94	(0.92,0.96)	0.1	0	mg/dL

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Add Health
The National Longitudinal Study of Adolescent to Adult Health

Quality Control

Summary

- High to date!
- Still some room for improvement
- To that end, we are
  - targeting the problems I highlighted
  - intervening to attenuate them
  - monitoring intervention effects

BIRTH RECORDS

Birth Records

Significance

Perinatal Data as…

- Outcomes
- Predictors

Birth Records

Goals

Adult Records

- 8 states
- 1974-1983
- 6,000+ records

Child Records

- 7 states
- 1988 – present
- 5,000+ records

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NC VITAL RECORDS

CERTIFICATE OF LIVE BIRTH

Registration District No. _____ Local No. _____ BIRTH NO. _____

CHILD

1. CHILD'S NAME (First, Middle, Last, Suffix)
2. DATE OF BIRTH (Month, Day, Year)
3. TIME OF BIRTH
4. SEX
5. FACILITY NAME (If not institution, give street and number)
6. CITY, TOWN, OR LOCATION OF BIRTH
7. COUNTY OF BIRTH

FATHER

8a. FATHER'S CURRENT LEGAL NAME (First, Middle, Last, Suffix)
8b. DATE OF BIRTH (Month, Day, Year)
8c. BIRTHPLACE (State, Territory, or Foreign Country)

MOTHER

9a. MOTHER'S CURRENT LEGAL NAME (First, Middle, Last, Suffix)
9b. DATE OF BIRTH (Month, Day, Year)
9c. MOTHER'S NAME PRIOR TO FIRST MARRIAGE (First, Middle, Last, Suffix)
9d. BIRTHPLACE (State, Territory, or Foreign Country)
10a. RESIDENCE OF MOTHER - STATE
10b. COUNTY
10c. CITY, TOWN, OR LOCATION
10d. STREET AND NUMBER
10e. ZIP CODE
10f. INSIDE CITY LIMITS? ☐ Yes ☐ No
11. MOTHER'S MAILING ADDRESS: ☐ Same as residence, or State: City, Town, or Location:
Street and Number: Zip Code:

CERTIFIER

12. CERTIFIER'S NAME:
TITLE: ☐ MD ☐ DO ☐ HOSPITAL ADMIN. ☐ CNM/CM ☐ OTHER MIDWIFE ☐ OTHER (Specify)
13. DATE CERTIFIED MM DD YYYY
14. DATE RECD BY LOCAL REGISTRAR MM DD YYYY
15. DATE NAME ADDED MM DD YYYY
16. DATE AMENDED MM DD YYYY

NEWBORN

17. BIRTHWEIGHT (grams preferred, specify unit) ☐ grams ☐ lb/oz
18. PLURALITY - Single, Twin, Triplet, etc. (Specify)
19. IF NOT SINGLE BIRTH - Born First, Second, Third, etc. (Specify)

RACE

20. FATHER'S RACE (Check one or more races to indicate what the father considers himself to be)
☐ White ☐ Black or African American ☐ American Indian or Alaska Native (Name of the enrolled or principal tribe) ☐ Asian Indian ☐ Chinese ☐ Filipino ☐ Japanese ☐ Korean ☐ Vietnamese ☐ Other Asian (Specify) ☐ Native Hawaiian ☐ Guamanian or Chamorro ☐ Samoan ☐ Other Pacific Islander (Specify) ☐ Other (Specify)

21. MOTHER'S RACE (Check one or more races to indicate what the mother considers herself to be)
☐ White ☐ Black or African American ☐ American Indian or Alaska Native (Name of the enrolled or principal tribe) ☐ Asian Indian ☐ Chinese ☐ Filipino ☐ Japanese ☐ Korean ☐ Vietnamese ☐ Other Asian (Specify) ☐ Native Hawaiian ☐ Guamanian or Chamorro ☐ Samoan ☐ Other Pacific Islander (Specify) ☐ Other (Specify)

22. MOTHER MARRIED? (At birth, conception, or any time between) ☐ Yes ☐ No
IF NO, HAS PATERNITY ACKNOWLEDGMENT BEEN SIGNED IN THE HOSPITAL? ☐ Yes ☐ No

23. SOCIAL SECURITY NUMBER REQUESTED FOR CHILD? ☐ Yes ☐ No

INFORMATION FOR MEDICAL AND HEALTH USE ONLY

FATHER

24. FATHER'S SOCIAL SECURITY NUMBER: ___-___-___
25. FATHER OF HISPANIC ORIGIN? (Check the box that best describes whether the father is Spanish/Hispanic/Latino. Check the "No" box if father is not Spanish/Hispanic/Latino)
☐ No, not Spanish/Hispanic/Latino
☐ Yes, Mexican, Mexican American, Chicano
☐ Yes, Puerto Rican
☐ Yes, Cuban
☐ Yes, other Spanish/Hispanic/Latino (Specify)
26. FATHER'S EDUCATION (Check the box that best describes the highest degree or level of school completed at the time of delivery)
☐ 8th grade or less
☐ 9th - 12th grade, no diploma
☐ High school graduate or GED completed
☐ Some college credit but no degree
☐ Associate degree (e.g., AA, AS)
☐ Bachelor's degree (e.g., BA, AB, BS)
☐ Master's degree (e.g., MA, MS, MEng, MEd, MSW, MBA)
☐ Doctorate (e.g., PhD, EdD) or Professional degree (e.g., MD, DDS, DVM, LLB, JD)

MOTHER

27. MOTHER'S SOCIAL SECURITY NUMBER: ___-___-___
28. MOTHER OF HISPANIC ORIGIN? (Check the box that best describes whether the mother is Spanish/Hispanic/Latina. Check the "No" box if mother is not Spanish/Hispanic/Latina)
☐ No, not Spanish/Hispanic/Latina
☐ Yes, Mexican, Mexican American, Chicana
☐ Yes, Puerto Rican
☐ Yes, Cuban
☐ Yes, other Spanish/Hispanic/Latina (Specify)
29. MOTHER'S EDUCATION (Check the box that best describes the highest degree or level of school completed at the time of delivery)
☐ 8th grade or less
☐ 9th - 12th grade, no diploma
☐ High school graduate or GED completed
☐ Some college credit but no degree
☐ Associate degree (e.g., AA, AS)
☐ Bachelor's degree (e.g., BA, AB, BS)
☐ Master's degree (e.g., MA, MS, MEng, MEd, MSW, MBA)
☐ Doctorate (e.g., PhD, EdD) or Professional degree (e.g., MD, DDS, DVM, LLB, JD)

30. PLACE WHERE BIRTH OCCURRED (Check one)
☐ Hospital
☐ Freestanding birthing center
☐ Home Birth:
Planned to deliver at Home? ☐ Yes ☐ No
☐ Clinic/Doctor's office
☐ Other (Specify)
31. FACILITY ID. (NPI)
32. ATTENDANT'S NAME, TITLE, AND NPI
NAME:
NPI:
TITLE: ☐ MD ☐ DO ☐ CNM/CM ☐ OTHER MIDWIFE ☐ OTHER: (Specify)
33. MOTHER TRANSFERRED FOR MATERNAL MEDICAL OR FETAL INDICATIONS FOR DELIVERY? ☐ Yes ☐ No
IF YES, ENTER NAME OF FACILITY MOTHER TRANSFERRED FROM:

MOTHER

34a. DATE OF FIRST PRENATAL CARE VISIT MM DD YYYY ☐ No Prenatal Care
34b. DATE OF LAST PRENATAL CARE VISIT MM DD YYYY
35. TOTAL NUMBER OF PRENATAL VISITS FOR THIS PREGNANCY (If none, enter "0".)
36. MOTHER'S HEIGHT (feet/inches)
37. MOTHER'S PREPREGNANCY WEIGHT (pounds)
38. MOTHER'S WEIGHT AT DELIVERY (pounds)
39. DID MOTHER GET WIC FOOD FOR HERSELF DURING THIS PREGNANCY? ☐ Yes ☐ No
40. NUMBER OF PREVIOUS LIVE BIRTHS (Do not include this child)
41. NUMBER OF OTHER PREGNANCY OUTCOMES (spontaneous or induced losses or ectopic pregnancies)
42. CIGARETTE SMOKING BEFORE AND DURING PREGNANCY
For each time period, enter either the number of cigarettes or the number of packs of cigarettes smoked. IF NONE, ENTER "0". Average number of cigarettes or packs of cigarettes smoked per day.

	# of cigarettes	OR	# of packs
Three months before pregnancy		OR	
First three months of pregnancy		OR	
Second three months of pregnancy		OR	
Third trimester of pregnancy		OR	

43. PRINCIPAL SOURCE OF PAYMENT FOR THIS DELIVERY
☐ Private Insurance ☐ Medicaid ☐ Self-Pay ☐ Other (Specify)
43a. Now Living Number ☐ None
43b. Now Dead Number ☐ None
41a. Other Outcomes Number ☐ None
43c. DATE OF LAST LIVE BIRTH MM YYYY
41b. DATE OF LAST OTHER PREGNANCY OUTCOME MM YYYY
44. DATE LAST NORMAL MENSES BEGAN MM DD YYYY
45. MOTHER'S MEDICAL RECORD NUMBER

MEDICAL AND HEALTH INFORMATION

46. RISK FACTORS IN THIS PREGNANCY (Check all that apply)
Diabetes
☐ Prepregnancy (Diagnosis prior to this pregnancy)
☐ Gestational (Diagnosis in this pregnancy)
Hypertension
☐ Prepregnancy (Chronic)
☐ Gestational (PIH, preeclampsia)
☐ Eclampsia
☐ Previous preterm birth
☐ Other previous poor pregnancy outcome (Includes perinatal death, small-for-gestational age/intrauterine growth restricted birth)
☐ Pregnancy resulted from infertility treatment--If yes, check all that apply:
☐ Fertility-enhancing drugs, Artificial insemination or intrauterine insemination
☐ Assisted reproductive technology (e.g., in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT)
☐ Mother had a previous cesarean delivery
If yes, how many
☐ None of the above

47. INFECTIONS PRESENT AND/OR TREATED DURING THIS PREGNANCY (Check all that apply)
☐ Gonorrhea
☐ Syphilis
☐ Chlamydia
☐ Hepatitis B
☐ Hepatitis C
☐ None of the above
Was mother tested for HBsAG? ☐ Yes ☐ No
If tested, include test date MM DD YYYY
and test results: ☐ Positive ☐ Negative

48. OBSTETRIC PROCEDURES (Check all that apply)
☐ Cervical cerclage
☐ Tocolysis
External cephalic version:
☐ Successful
☐ Failed
☐ None of the above

49. ONSET OF LABOR (Check all that apply)
☐ Premature Rupture of Membranes (prolonged, ≥12 hrs.)
☐ Precipitous Labor (<3 hrs.)
☐ Prolonged Labor (≥ 20 hrs.)
☐ None of the above

50. CHARACTERISTICS OF LABOR AND DELIVERY (Check all that apply)
☐ Induction of labor
☐ Augmentation of labor
☐ Non-vertex presentation
☐ Steroids (glucocorticoids) for fetal lung maturation received by the mother prior to delivery
☐ Antibiotics received by the mother during labor
☐ Clinical chorioamnionitis diagnosed during labor or maternal temperature ≥ 38°C (100.4°F)
☐ Moderate/heavy meconium staining of the amniotic fluid
☐ Fetal intolerance of labor such that one or more of the following actions was taken: in-utero resuscitative measures, further fetal assessment, or operative delivery
☐ Epidural or spinal anesthesia during labor
☐ None of the above

51. METHOD OF DELIVERY
A. Was delivery with forceps attempted but unsuccessful? ☐ Yes ☐ No
B. Was delivery with vacuum extraction attempted but unsuccessful? ☐ Yes ☐ No
C. Fetal presentation at birth ☐ Cephalic ☐ Breech ☐ Other
D. Final route and method of delivery (Check one)
☐ Vaginal/Spontaneous
☐ Vaginal/Forceps
☐ Vaginal/Vacuum
☐ Cesarean
If cesarean, was a trial of labor attempted? ☐ Yes ☐ No

52. MATERNAL MORBIDITY (Check all that apply)
(Complications associated with labor and delivery)
☐ Maternal transfusion
☐ Third or fourth degree perineal laceration
☐ Ruptured uterus
☐ Unplanned hysterectomy
☐ Admission to intensive care unit
☐ Unplanned operating room procedure following delivery
☐ None of the above

NEWBORN INFORMATION

NEWBORN

53. NEWBORN MEDICAL RECORD NUMBER:
54. OBSTETRIC ESTIMATE OF GESTATION: (completed weeks)
55. APGAR SCORE:
Score at 5 minutes:
If 5 minute score is less than 6, Score at 10 minutes:
56. INFANT VACCINATION
Infant vaccinated with Hepatitis B vaccine? ☐ Yes ☐ No
If yes, include vaccination date MM DD YYYY

57. ABNORMAL CONDITIONS OF THE NEWBORN (Check all that apply)
☐ Assisted ventilation required immediately following delivery
☐ Assisted ventilation required for more than six hours
☐ NICU admission
☐ Newborn given surfactant replacement therapy
☐ Antibiotics received by the newborn for suspected neonatal sepsis
☐ Seizure or serious neurologic dysfunction
☐ Significant birth injury (skeletal fracture(s), peripheral nerve injury, and/or soft tissue/solid organ hemorrhage which requires intervention)
☐ None of the above

58. CONGENITAL ANOMALIES OF THE NEWBORN (Check all that apply)
☐ Anencephaly
☐ Meningomyelocele/Spina bifida
☐ Cyanotic congenital heart disease
☐ Congenital diaphragmatic hernia
☐ Omphalocele
☐ Gastroschisis
☐ Limb reduction defect (excluding congenital amputation and dwarfing syndromes)
☐ Cleft Lip with or without Cleft Palate
☐ Cleft Palate alone
☐ Down Syndrome
☐ Karyotype confirmed
☐ Karyotype pending
☐ Suspected chromosomal disorder
☐ Karyotype confirmed
☐ Karyotype pending
☐ Hypospadias
☐ None of the anomalies listed above

59. WAS INFANT TRANSFERRED WITHIN 24 HOURS OF DELIVERY? ☐ Yes ☐ No
IF YES, NAME OF FACILITY INFANT TRANSFERRED TO:
60. IS INFANT LIVING AT TIME OF REPORT? ☐ Yes ☐ No ☐ Infant transferred, status unknown
61. IS THE INFANT BEING BREASTFED AT DISCHARGE? ☐ Yes ☐ No

Summary of Available Information on State-Level Birth Records, 1974-1983

Birth outcomes

- Birth weight
- Gestation length
- Apgar (5-minute)

Infant characteristics

- Infant sex
- Birth order (singleton; 1st twin; 2nd twin; etc.)

Pregnancy characteristics / hx

- Plurality
- Month prenatal care began
- Total number of prenatal visits
- Date of last live birth
- Medical risk factors (e.g., gestational diabetes)[1]
- Complications related to pregnancy
- Total live births now living/now dead

Delivery characteristics

- Labor/delivery complications
- Hospital size (e.g., < 20 beds; 100+ beds; etc)
- Birth attendant (physician; midwife; etc)

Parents' characteristics

- Mother's and father's age
- Mother's and father's race
- Marital status
- Mother's and father's education (years)
- Mother's and father's state/country of birth

Personal identifiers for linking

- Child's date of birth (mmddyy)
- Child's first, middle, last name
- Mother's maiden name (first, middle, last)
- Mother's complete residence address
- Father's first, middle, last name

Surveillance of Chronic Disease Events

Add Health Design

- Nationally representative
  - region
  - population density
  - school size / type
  - ethnicity
- School-based sample, students grades 7-12 (n=20,745)
  - 80 high schools
  - 52 feeder schools
- Longitudinal

Wave	Years	Mode	Response Rate	Age (yr)
I	‘94-’95	in-school & in-home	79%	} 12-20
II	‘96	in-home	88%	
III	‘01-’02	in-home	77%	18-26
IV	‘07-’09	in-home	80%	24-32
V	’16-’18	mixed		32-42

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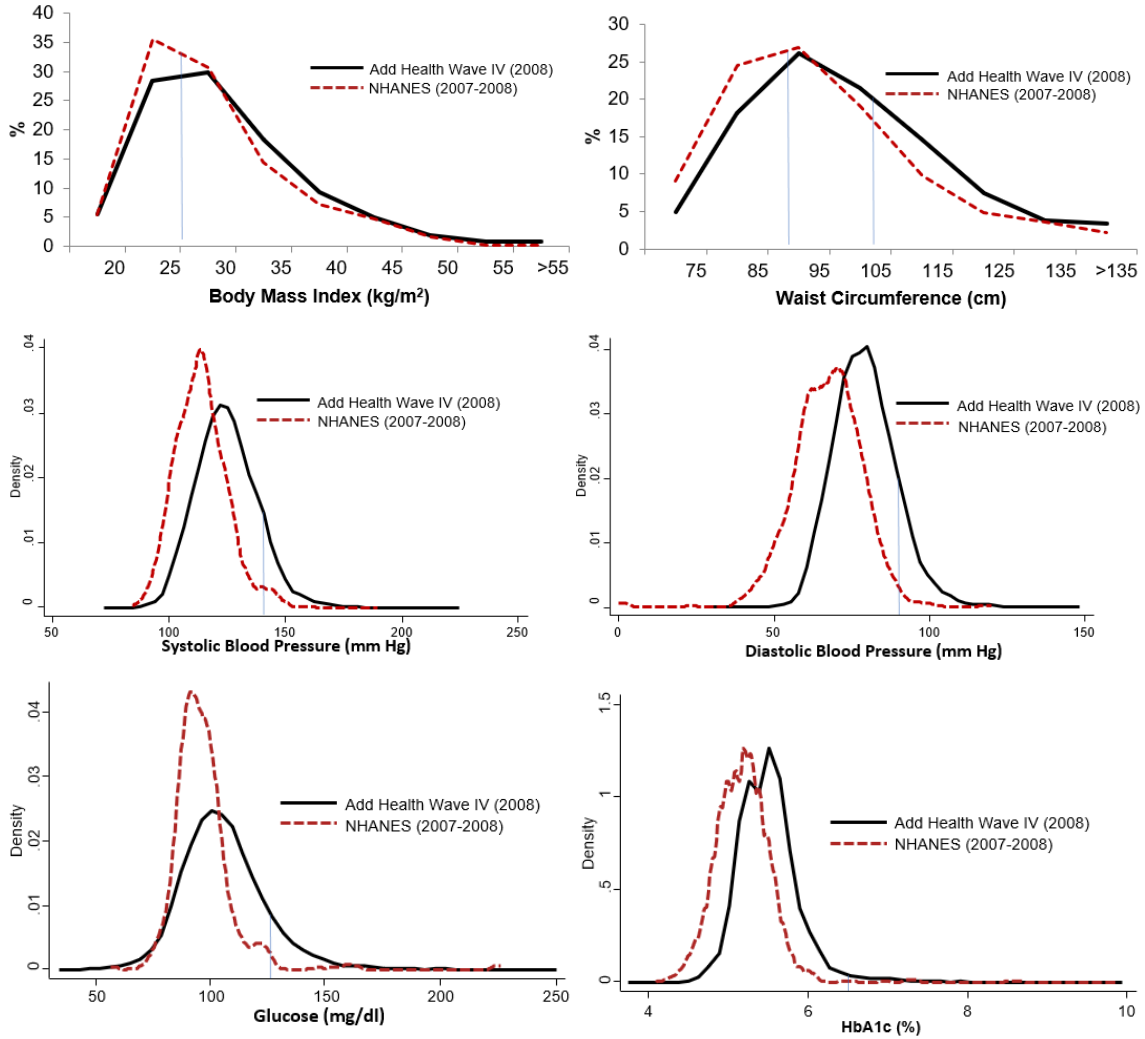
Surveillance of Chronic Disease Events

Risk Factor Distributions @ Wave IV



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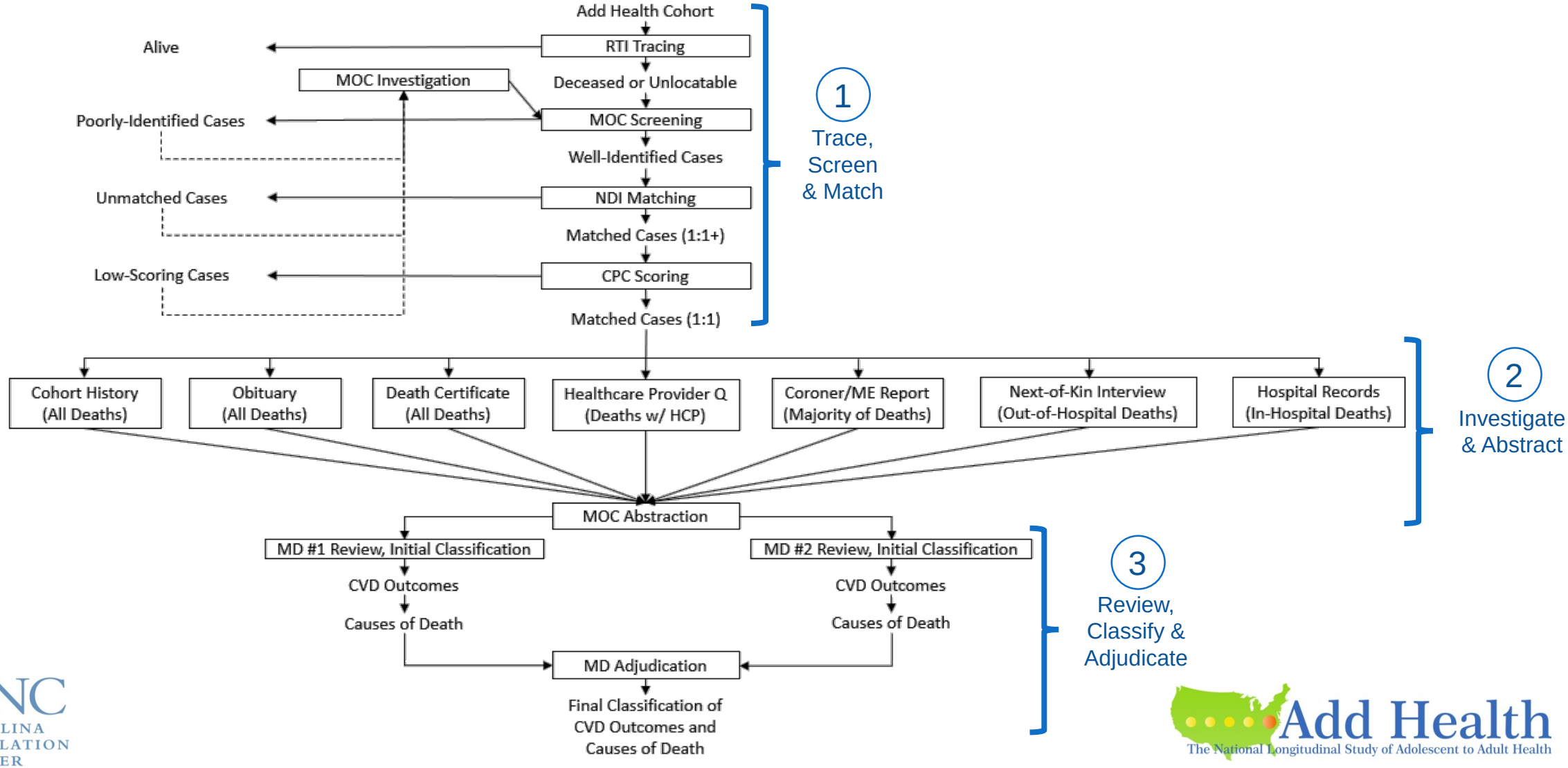
Surveillance of Chronic Disease Events

Surveillance Infrastructure @ Wave V



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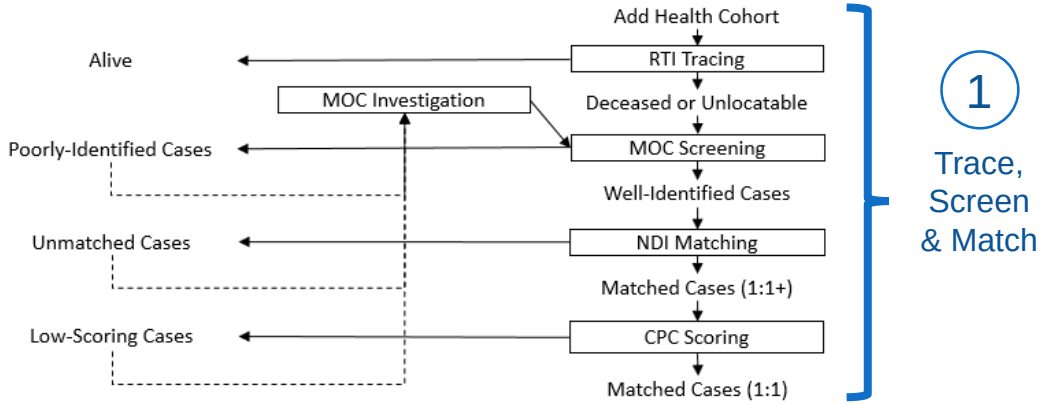
Surveillance of Chronic Disease Events

Component Progress: Tracing, Screening & Matching

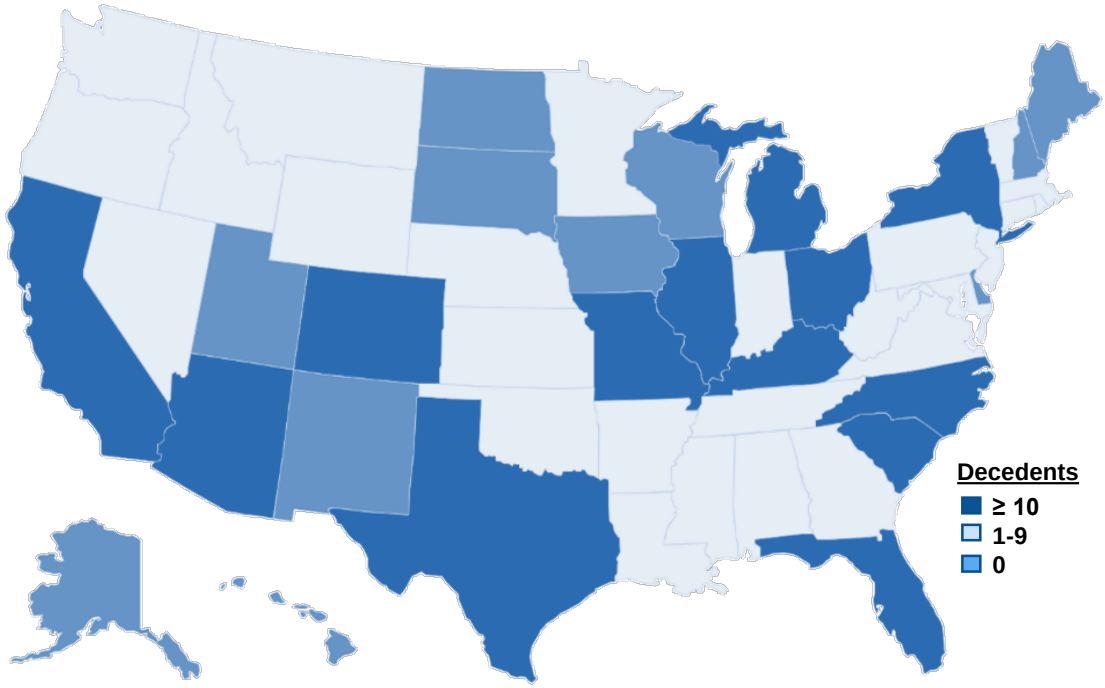


Case Status	Wave III	Wave IV	Wave V	Total
Deceased or Unlocatable	96	131	168	395
Well-Identified (sent to NDI)	96	131	150*	377
Matched (1:1)	84 (88%)	118 (90%)	140 (93%)	342 (91%)

*Eighteen recently identified cases are pending NDI submission.

Surveillance of Chronic Disease Events

Geographic Distribution of U.S. Deaths



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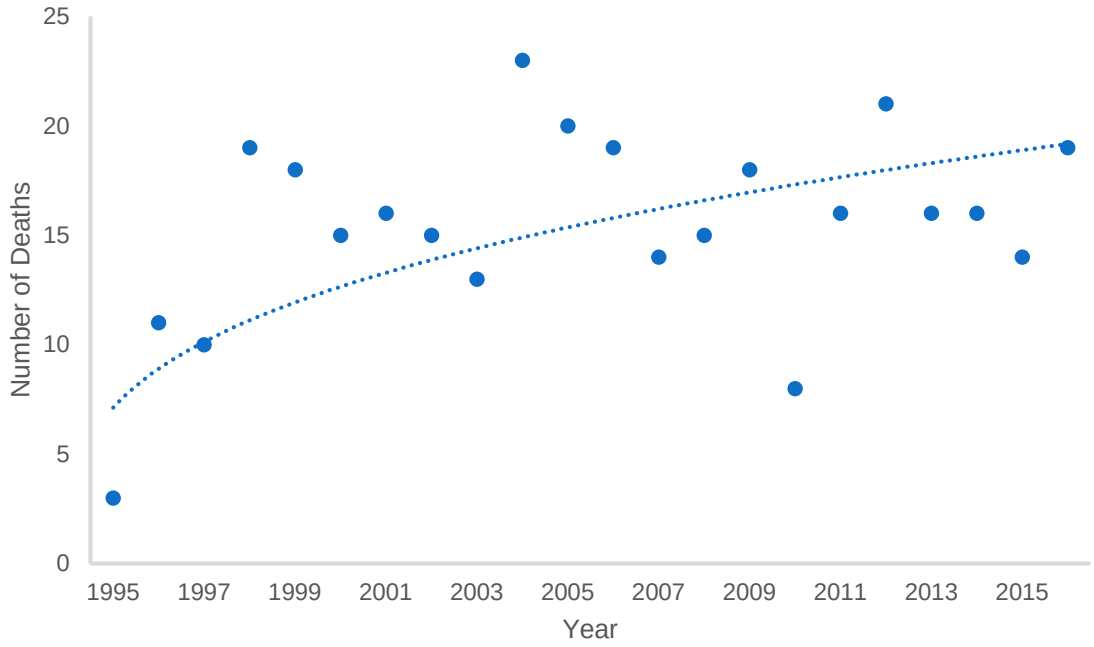
Surveillance of Chronic Disease Events

Temporal Distribution of Deaths*



*Includes 325 NDI matches; 9 international or recent, but obituary / death certificate-confirmed deaths; and 10 deaths pending NDI submission.

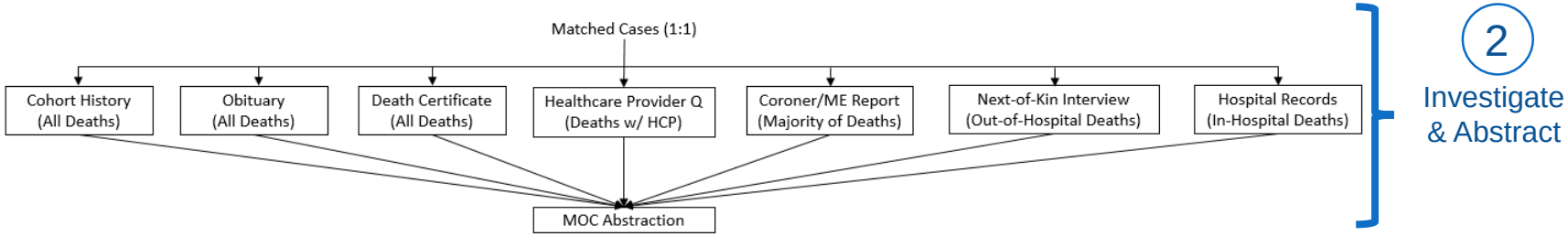
Surveillance of Chronic Disease Events

Demographic Distribution of All Deaths

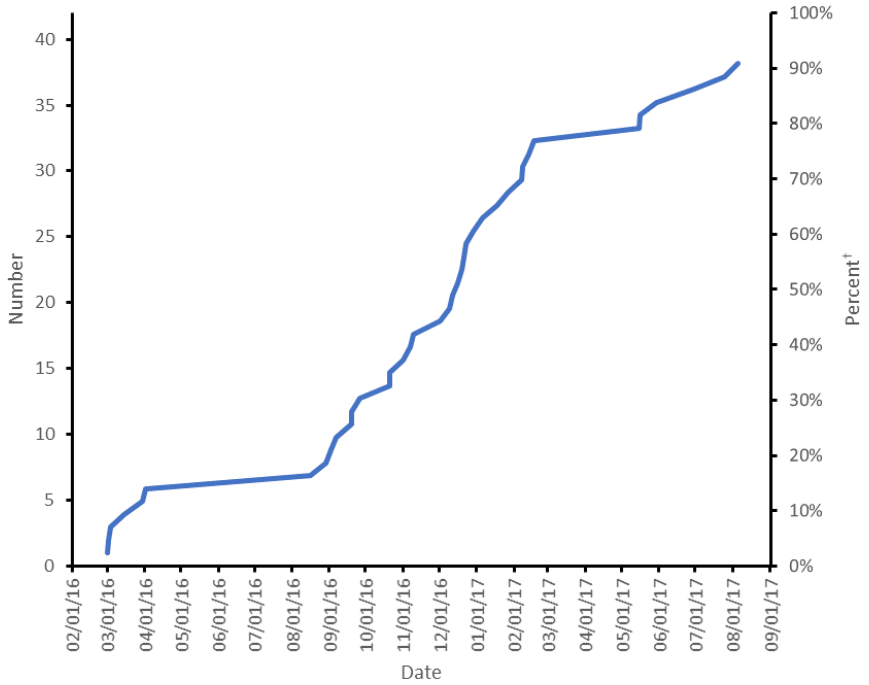
Characteristic	Mean (Range) or %
Age, years	26.9 (22-39)
Female	33%
Race/ethnicity EA	53%
AA	23%
HL	9%
A/PI	3%
AI/AN	2%
O/M	10%

Surveillance of Chronic Disease Events

Component Progress: Investigation & Abstraction



Execution of 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. Of 37 agreements, 27 (73%) are with "closed" record states that required Vital Records / Statistics IRB reviews. Agreement duration range: 1-5 years.

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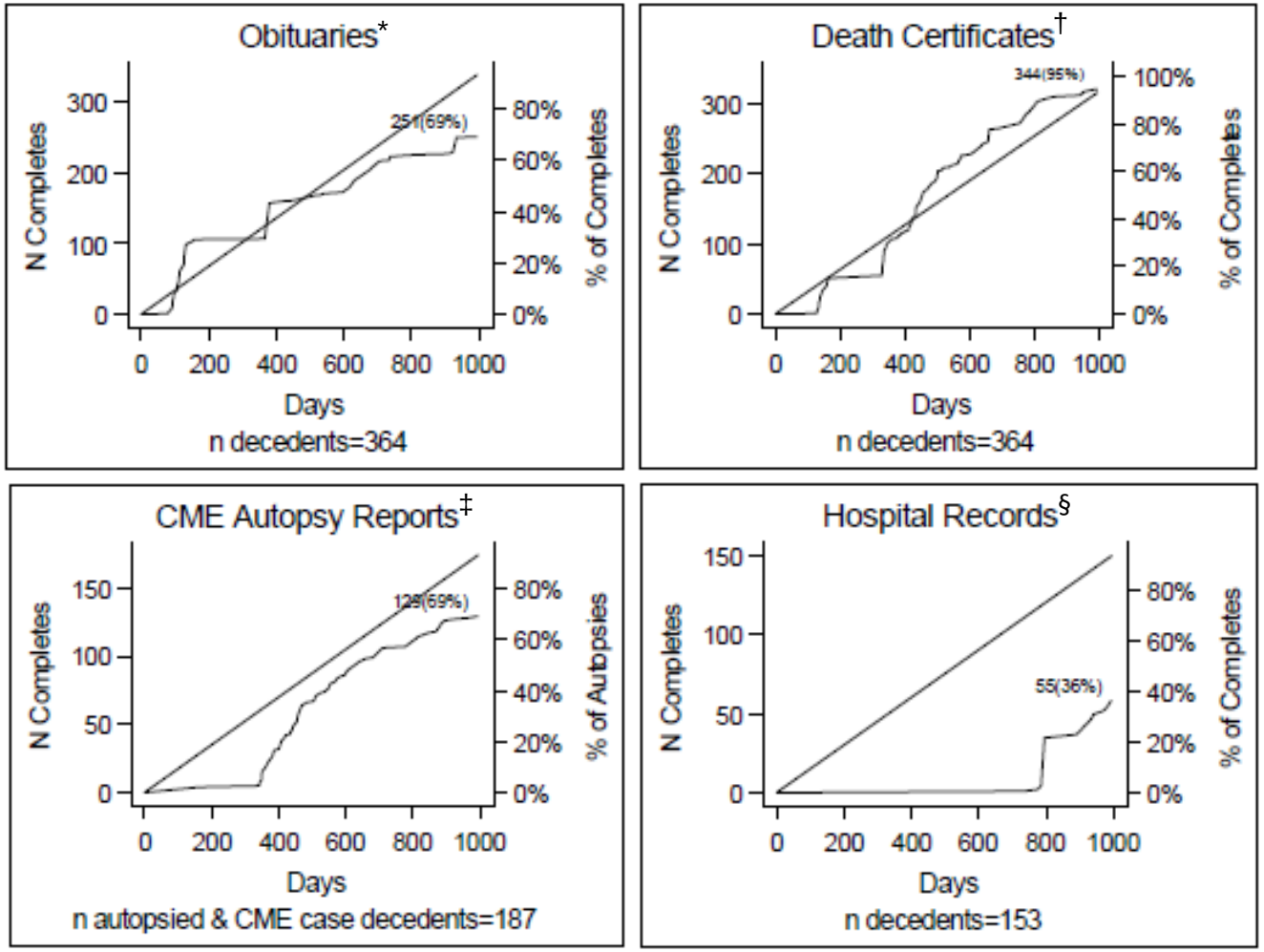
Surveillance of Chronic Disease Events

Component Progress: Investigation & Abstraction



*Not published for all deaths. †Not releasable for 2 (<1%) of 364 deaths. ‡Not releasable for 52 (28%) of 187 deaths. §Unavailable for 45 (29%) and 26 (17%) of 153 deaths either purged or without consent/authorization.

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Surveillance of Chronic Disease Events

Surveillance Data Quality Control

Median (Range) Item-Specific Agreement

Abstraction Form	Agreement	κ*
Obituary	0.86 (0.84-0.89)	0.83 (0.80-0.86)
Coroner/Medical Examiner Report	0.90 (0.87-0.93)	0.86 (0.83-0.90)
Death Certificate	0.93 (0.92-0.95)	0.92 (0.90-0.94)

*Prevalence & bias-adjusted kappa coefficient

Surveillance of Chronic Disease Events

Manner & Underlying Cause of NDI-Matched Deaths

Manner*	%
Accidental	42.9
Natural	27.2
Suicide	14.6
Homicide	12.7
Unidentified	2.6

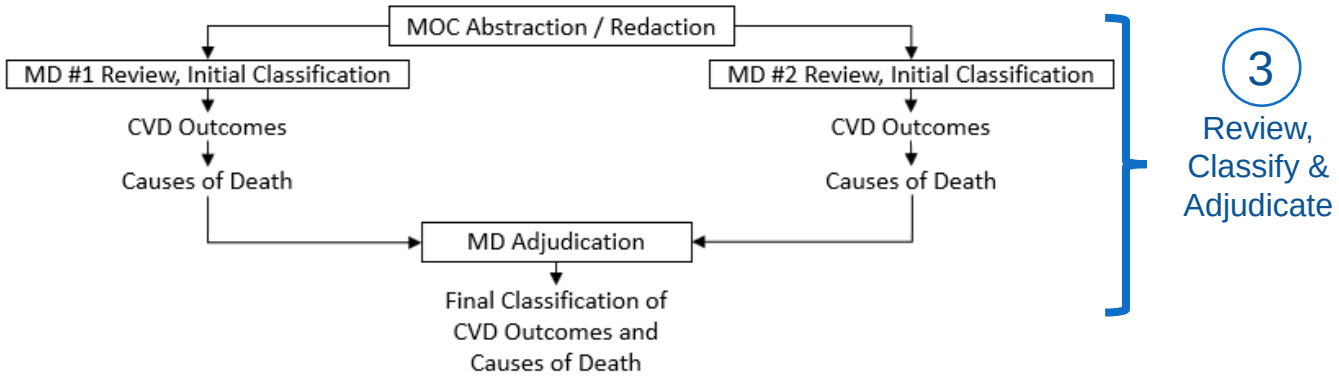
*From death certificate

Underlying Cause*	%
Motor Vehicle Accident	24.3
Suicide	13.8
Accidental Drug Intoxication	12.0
Cardiovascular Disease	11.1
Homicide	9.8
Cancer	6.5
Infectious Disease	6.2
Other Accident	4.9

*From ICD codes (NDI)

Surveillance of Chronic Disease Events

Component Progress: Review, Classification & Adjudication



In Progress!

Surveillance of Chronic Disease Events

Summary

- Death & CVD Outcome Surveillance ongoing in this
  - Nationally representative
  - School-based
  - Longitudinal
  - Study of adolescence to mid-adulthood
- 364 deaths identified
- Most successfully investigated
- Preliminarily, > 25% due to natural causes
- Review, classification & adjudication in progress
- Stay tuned re data access!

Wave V Biology Project

Importance of Biological Data

- One of Add Health's main strengths is its data
  - rich, high-quality
  - nationally representative & longitudinal
  - individual, multi-contextual and biological
- Collectively, the data constitute a valuable resource
- The resource can be leveraged toward understanding population health