

National Health and Nutrition Examination Survey (NHANES)

Alan E. Simon, MD Director, Division of Health and Nutrition Examination Surveys National Center for Health Statistics

History and Accomplishments

An Evolving Survey Since 1959



History of NHANES

| Survey | Dates | Ages |
|------------|--------------|---------------------|
| NHES I | 1959 – 62 | 18 – 79 years |
| NHES II | 1963 – 65 | 6 – 11 years |
| NHES III | 1966 – 70 | 12 – 17 years |
| NHANES I | 1971 – 75 | 1 – 74 years |
| NHANES II | 1976 – 80 | 6 months – 74 years |
| HHANES | 1982 – 84 | 6 months – 74 years |
| NHANES III | 1988 – 94 | 2 months + |
| NHANES | 1999-Present | All Ages |

NHES = National Health Examination Survey; NHANES = National Health And Nutrition Examination Survey; HHANES = Hispanic Health And Nutrition Examination Survey



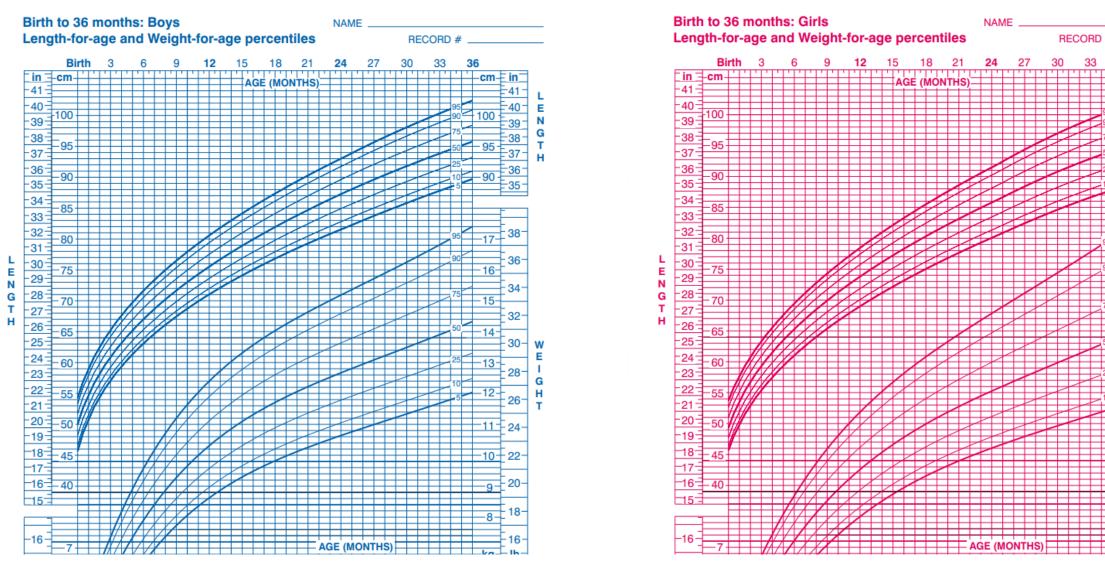
Accomplishments – Nutrition

➤ NHANES identified low iron levels as a serious problem especially for women of childbearing age, preschool children, and the elderly. As a result, the government decided to fortify grain and cereal with iron.

➤ NHANES data informed a 2016 U.S. Food and Drug Administration (FDA) decision to **permit fortification of corn masa flour with folic acid** to address neural tube birth defects particularly among the nation's Hispanic population.



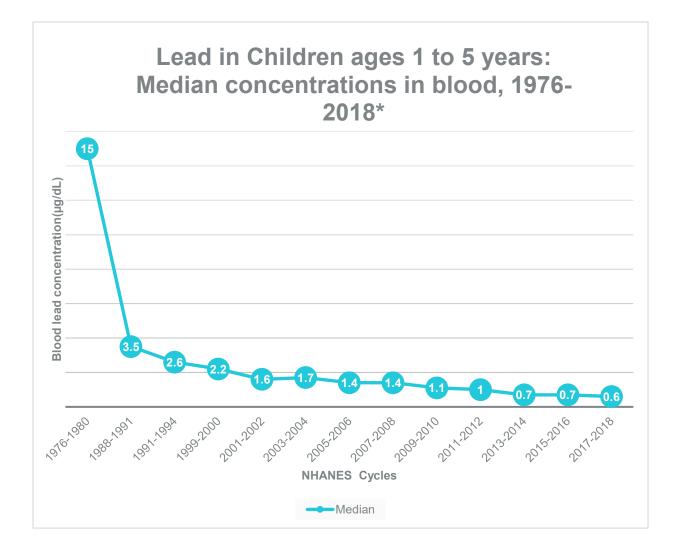
Accomplishments – CDC Growth Charts



> Used nationally by pediatricians to evaluate children's growth

Accomplishments – Lead

- ➤ Since 1976, blood lead levels in the U.S. population are measured in NHANES gave the first clear-cut evidence that Americans had too much lead in their blood.
- This led Congress, the Environmental Protection Agency, and others to phase out the use of lead as an additive in gasoline.





Goals

Goal of NHANES

- To produce population-based prevalence estimates and trends on:
 - Health conditions and risk factors
 - Nutrition status and diet behavior
 - Prescription medication and dietary supplement use
 - Environmental exposures
- To establish and maintain a biospecimen program



Sampling Design

NHANES – Nationally Representative







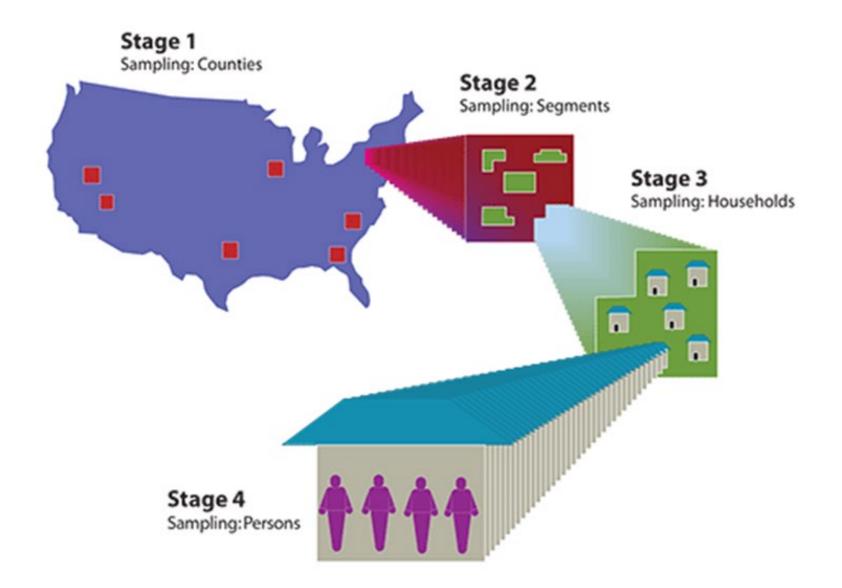
Overview

- Cross-sectional
- Noninstitutionalized civilian resident population
- Information is collected through:
 - In-person home interviews
 - Health examinations
- Target sample: 5,000 individuals examined annually
- Previously oversampled groups:
 - Non-Hispanic Black, Asian, Hispanic
 - Aged 80+ years
 - Low-income non-Hispanic White
- Data released in 2-year cycles





Multistage Probability Sampling Design





Data Collection

From Sample Selection to Examination







Screening at Household Doorstep



Household Interview



Examination at Mobile Examination Center (MEC)

Consent obtained for Interview

for examination, future studies ie DNA (past years)



Home Interview

- Demographic information
- Health conditions
- Health insurance and healthcare use
- Prescription drugs and dietary supplements use







Mobile Examination Center



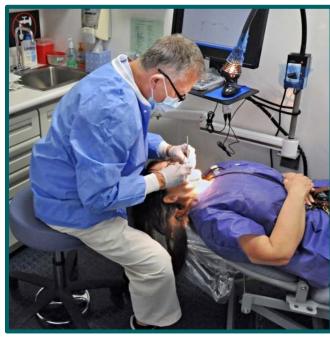


MEC Examinations











Exam measures differ by age and survey year

Table 3. Examination components: National Health and Nutrition Examination Survey, 1999-2022



| | r laboratory test conducted | | | | Change from | - | | | • | r laboratory t | | | |
|--|-----------------------------|-----------|-----------|-----------|-------------|-----------|-----------|-----------|-----------|----------------|-----------|-----------|----------|
| Component | Sample description | 1999-2000 | 2001–2002 | 2003-2004 | 2005-2006 | 2007–2008 | 2009-2010 | 2011–2012 | 2013-2014 | 2015–2016 | 2017–2018 | 2019–2020 | 2021–202 |
| Arthritis body measures | 20-69 years | | | | | | | <u> </u> | | | | | |
| Audiometry | 1/2 sample (20–69 years) | | | | | | | | | | | | |
| Balance | 1/2 sample (40–69 years) | | | | | | | | | | | | |
| Bioelectrical impedance analysis | 8-49 years | | | | | | | | | | | | |
| Blood pressure | 8 years and over | | | | | | | | | | | | |
| Body measurements | All ages | | | | | | | | | | | | |
| Cardiovascular (CV) fitness | 12-49 years | | | | | | | | | | | | |
| Cognitive functioning | 60 years and over | | | | | | | | | | | | |
| Dermatology | 20-59 years | | | | | | | | | | | | |
| Dietary | All ages | | | | | | | | | | | | |
| Dietary supplement | All ages | | | | | | | | | | | | |
| Dual energy x-ray absorptiometry | 8 years and over | | | | | | | | | | | | |
| Abdominal aortic calcification | 40 years and over | | | | | | | | | | | | |
| Body composition | 8 years and over | | | | | | | | | | | | |
| Bone density—Hip and spine | 8 years and over | | | | | | | | | | | | |
| Vertebral fracture assessment | 40 years and over | | | | | | | | | | | | |
| Grip strength test | 6 years and over | | | | | | | | | | | | |
| Liver ultrasound transient elastography | 12 years and over | | | | | | | | | | | | |
| Lower extremity disease | 40 years and over | | | | | | | | | | | | |
| Peripheral neuropathy | 40 years and over | | | | | | | | | | | | |
| Peripheral vascular disease | 40 years and over | | | | | | | | | | | | |
| Ophthalmology | 40 years and over | | | | | | | | | | | | |
| Retinal photo | 40 years and over | | | | | | | | | | | | |
| Visual fields | 40 years and over | | | | | | | | | | | | |
| Oral health | 2 years and over | | | | | | | | | | | | |
| Dental fluorosis imaging | 6–19 years | | | | | | | | | | | | |
| Physical activity monitor | 6 years and over | | | | | | | | | | | | |
| Muscle strength | 50 years and over | | | | | | | | | | | | |

Complete list available: https://wwwn.cdc.gov/nchs/data/nhanes/survey-contents-508.pdf



Laboratory Tests

- In a 2-year cycle, NHANES runs ~500 assays in over 22 laboratories
- Each assay is run at only one lab to minimize method effects
- Examples include:
 - <u>Environmental exposures</u> such as lead, arsenic, mercury, pesticides, & flame retardants
 - Infectious disease profiles such as Hepatitis B and C, HIV, chlamydia, & cytomegalovirus
 - Nutritional biomarkers such as Vitamin D, retinol, fatty acids, and folate
 - Chronic disease profiles such as urine albumin for kidney disease, TSH for thyroid disease, hemoglobin AIC for diabetes, and a lipid profile for cardiovascular disease



Report of Findings

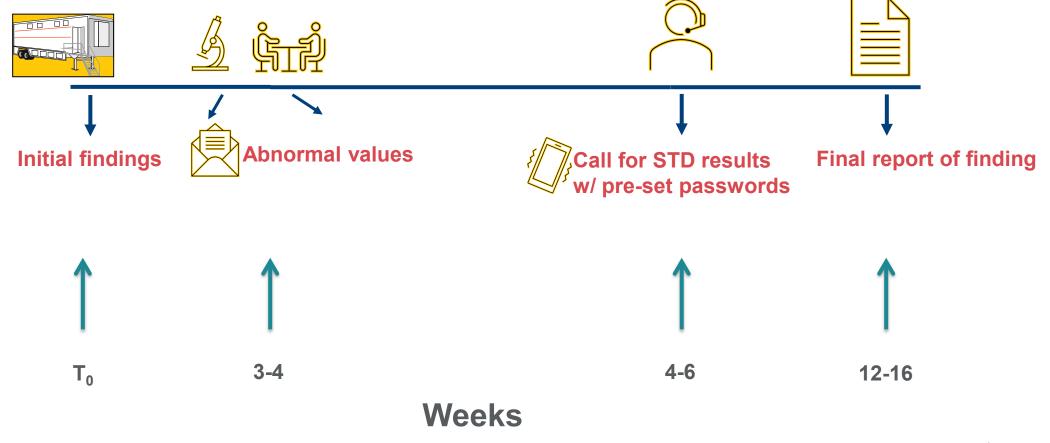
Current Standard for Report of Findings Determination

 For an NHANES result to be reported, it must be "clinically actionable" for participant and/or medical provider

- The findings are valid and, in the case of laboratory tests, done by a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory;
- The findings may have significant implications for the subjects' health concerns; and
- A course of action to ameliorate, or treat the concerns is readily available.



Timing for Report of Findings







National Health and Nutrition Examination Survey

Final Report of Findings

The final report of findings includes all clinically actionable findings and is mailed within 12-16 weeks following the participants' exams

Results Provided:

- Identifying information
- Height and weight
- Blood pressure & Heart Rate

These measurements were obtained as part of a survey and do not represent a medical diagnosis.

Interpretation of these measurements must be made by a physician.

 Date of Examination:
 DATE

 Participant Name:
 Participant

 Participant Age at Interview:
 xx years

 Participant Age at Exam:
 xx years

 Participant Gender:
 Female

 SP ID:
 123456

Body Measurements

 Height:
 5 ft. 4 in.

 Weight:
 122.9 lbs.

Blood Pressure & Heart Rate

ADULT (ages 18 years and up) Normal

Systolic Blood Pressure: 118 mm Hg < 120
Diastolic Blood Pressure: 76 mm Hg < 80

Resting Pulse Rate: 88 Cuff Size: Adult

Your blood pressure today is within the normal range based on the American Cardiology Association (ACC) and the American Heart Association (AHA) Hypertension Guidelines for Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults. American Journal of Hypertension, 2018; 31 (2):133-135.

CHILD (ages 8-17 years)

Systolic Blood Pressure: 105 mm Hg
Diastolic Blood Pressure: 65 mm Hg
Resting Pulse Rate: 94
Cuff Size: Child

Your child's blood pressure today is within the normal range based on the American Academy of Pediatrics (AAP) Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents. Pediatrics 2017; 140 (3):e20171904



SP ID, xx years, Female, 123456, Date

Results Provided:

Complete blood count



National Health and Nutrition Examination Survey

Final Report of Findings

| Complete Blood Count | | | | |
|----------------------|--------|----------------------|------|-----------------|
| | Result | Units | Flag | Reference Range |
| White Blood Count | 7.0 | x10°/L | | 4.1 - 12.9 |
| Lymphocytes | 21.8 | % | | 14.1 - 47.6 |
| Monocytes | 4.7 | % | | 3.8 - 11.6 |
| Neutrophils | 56.6 | % | | 39.8 - 78.1 |
| Eosinophils | 0.6 | % | | 0.6 - 7.3 |
| Basophils | 1.4 | % | | 0.1 - 1.7 |
| Red Blood Count | 4.7 | x10 ¹² /L | | 3.6 - 5.2 |
| NRBC | 0.0 | x10 ¹² /L | | 0.0 - 0.3 |
| Hemoglobin | 12.7 | g/dL | | 10.6 - 15.6 |
| Hematocrit | 38.0 | % | | 32.0 - 45.9 |
| MCV | 80.8 | fL | | 74.6 - 98.2 |
| MCH | 26.0 | pg | | 24.3 - 33.8 |
| MCHC | 33.4 | g/dL | | 32.1 - 35.3 |
| RDW | 14.5 | % | | 11.4 - 16.3 |
| Platelet Count | 360 | x10°/L | | 168 - 441 |



--- Test not don

A/A/A/ Results still pending

Lower than the limit of detection

>>> Above the limit of detection

ranz Delawed results

Number of hours fasted prior to blood draw: 22



Results Provided:

Blood Tests



National Health and Nutrition Examination Survey

Final Report of Findings

Blood Tests

| | Result | <u>Units</u> | Flag | Reference Range |
|------------------------------------|--------|--------------|------|---------------------|
| Glucose | 85 | mg/dL | | 60 - 109 |
| Hemoglobin A1c | 4.6 | % | | < 6.5 |
| ALT | 10 | IU/L | | < 31 |
| AST | 11 | IU/L | | < 31 |
| Alkaline Phosphatase | 60 | IU/L | | 39 - 117 |
| Albumin | 3.3 | g/dL | | 3.2 - 5.2 |
| Bicarbonate | 20 | mmol/L | Low | 22 - 29 |
| BUN | 7 | mg/dL | | 6 - 19 |
| Calcium | 10.0 | mg/dL | | 8.4 - 10.2 |
| Cholesterol | 182 | mg/dL | | < 200 |
| CPK | 30 | IU/L | | 22 - 199 |
| Triglycerides | 87 | mg/dL | | < 150 |
| HDL | 66 | mg/dL | | > 39 |
| Phosphorus | 4.1 | mg/dL | | 2.6 - 4.5 |
| Sodium | 136 | mmol/L | | 133 - 145 |
| Potassium | 4.00 | mmol/L | | 3.30 - 5.10 |
| Chloride | 102 | mmol/L | | 96 - 108 |
| Total Protein | 6.9 | g/dL | | 5.9 - 8.4 |
| Uric Acid | 3.7 | mg/dL | | 2.4 - 5.7 |
| Bilirubin | 0.2 | mg/dL | | 0.0 - 1.0 |
| Serum Folate | 48.8 | nmol/L | | 10.5 - 90.7 |
| RBC Folate | 1610 | nmol/L | | 640 - 2006 |
| Serum Ferritin | 48 | µg/L | | 15 - 150 |
| Iron | 63 | µg/dL | | 22 - 163 |
| Total Iron Binding Capacity (TIBC) | 344 | µg/dL | | 250 - 450 |
| Transferrin Saturation | 18 | % | Low | 20 - 50 |
| Lead | 0.5 | µg/dL | | 0.0 - 10.0 |
| Vitamin D | VVV | µg/dL | | |
| Cadmium | 0.1 | µg/L | | 0.3 - 1.2 |
| Total Blood Mercury | 0.6 | µg/L | | < 5.7 |
| Testosterone | 500 | µg/dL | | 250-1100 |
| Thyroglobulin | 5 | ng/ml | | 1.5-29.2 |
| TSH | 4 | mIU/dL | | 0.45-4.12 |
| Follicle Stimulating Hormone | 12 | mIU/mL | | Varies individually |
| Lutenizing Hormone | 15 | mIU/mL | | Varies individually |

--- Test not done

A/A/A Results Still Pending

Compare that the limit of detection Above the limit of detection

vvv Delayed Results

Number of hours fasted prior to blood draw: 22



SP ID, xx years, Female, 123456, Date Centers for Disease Control and Prevention, NCHS 3311 Toledo Road, MS P08, Hyattsville, Maryland 20782

Results Provided:

- Urine Tests
- Kidney Health



Urine Tests

| | Result | <u>Units</u> | Flag | Reference Range |
|---|--------|--------------|------|-----------------|
| Albumin Creatinine Ratio - 1st Collection | 7.17 | mg/g | | < 30.00 |
| Total Arsenic | | μg/L | | |
| Urinary Nickel | | μg/L | | |

Kidney Health

Your kidneys filter your blood and help control blood pressure. We checked how healthy your kidneys are by calculating your estimated glomerular filtration rate (eGFR). This is not a meaningful test if you are very muscular.

Your estimated glomerular filtration rate (eGFR) was 120 mL/min/1.73m²

This indicates normal function

This value is not meaningful for pregnant women, individuals with acute kidney failure, people with extreme body size or muscle mass (such as individuals who are bodybuilders, extremely obese or severely malnourished), and people on vegetarian or low-meat diets or taking creatine dietary supplements.

Above the limit of detection

Delayed Results

Results Provided:

- Body Composition
- Liver Elastography
- Balance



National Health and Nutrition Examination Survey Final Report of Findings

Body Composition

The whole-body scan provides information on your percent body fat.

The body composition exam results showed that your total body fat is ____%.

We do not know exactly what percent body fat is considered healthy for your age and gender. Researchers are working to define the healthy ranges for the public. You may want to discuss this result and your body measurement findings (page 1) with your doctor to find out what they mean for you. Too much body fat can increase a person's risk of getting diabetes or heart disease.

Liver Elastography

Liver elastography measures the stiffness of your liver. In general, having liver stiffness may indicate liver damage.

Information from your liver ultrasound exam showed a value of 3.60 kiloPascals (kPa).

A scoring system (1), was used to interpret your result. Using this recommended scoring system, the result showed you have little or no liver stiffness. No additional follow-up regarding this test is recommended at this time.

Published in GASTROENTEROLOGY 2005;128:343–350.

Balance

You performed a Modified Romberg test for balance during your examination. This screening test is listed by the Centers for Medicare and Medicaid (CMS) Physician Quality Reporting System for fall risk assessment.

SP, xx years, Female, 123456, Date Centers for Disease Control and Prevention, NCHS 3311 Toledo Road, MS P08, Hyattsville, Maryland 20782

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Returning Results - Additional notes

- NHANES has limited short-duration contact with participants (i.e., NHANES initiates its last contact with participants ~12-16 weeks following the exam)
- The mobile examination center is not a treatment facility and no health care is provided
- NHANES prepares lists of local clinics in advance of operations and provides recommendations for referral, if necessary
- NHANES does not pay for any follow-up health care



Future Direction

Looking to the future



National Health and Nutrition Examination Survey

New Content and Proposal Guidelines

Print

July 26, 2022

The Division of Health and Nutrition Examination Surveys has moved into the next phase of the 2024 NHANES redesign. If you have been invited to submit a full examination or laboratory proposal for consideration, please use these <u>Proposal</u> Guidelines.

At this time, we have not yet sent out invitations for submission of full proposals involving only questionnaire component(s). Anticipated timeframe for questionnaire proposal invitation is the second week of August.

If you have any questions about the Proposal Guidelines or the process, please email us at <u>DHANES_PB@cdc.gov</u>.

Sincerely,

David A. Woodwell
Chief, Planning Branch
Division of Health and Nutrition Examination Surveys
National Center for Health Statistics
Centers for Disease Control and Prevention

 In summer 2022, NHANES began solicitation of interview, exam, and lab content for its next data collection cycle

 This workshop will inform incorporating genomics into NHANES future data collection cycles



NHANES Website:

https://www.cdc.gov/nchs/nhanes/index.htm

Thank you



Biospecimen Program

Alan E. Simon, MD Director, Division of Health and Nutrition Examination Surveys National Center for Health Statistics

NHANES Biospecimen Program

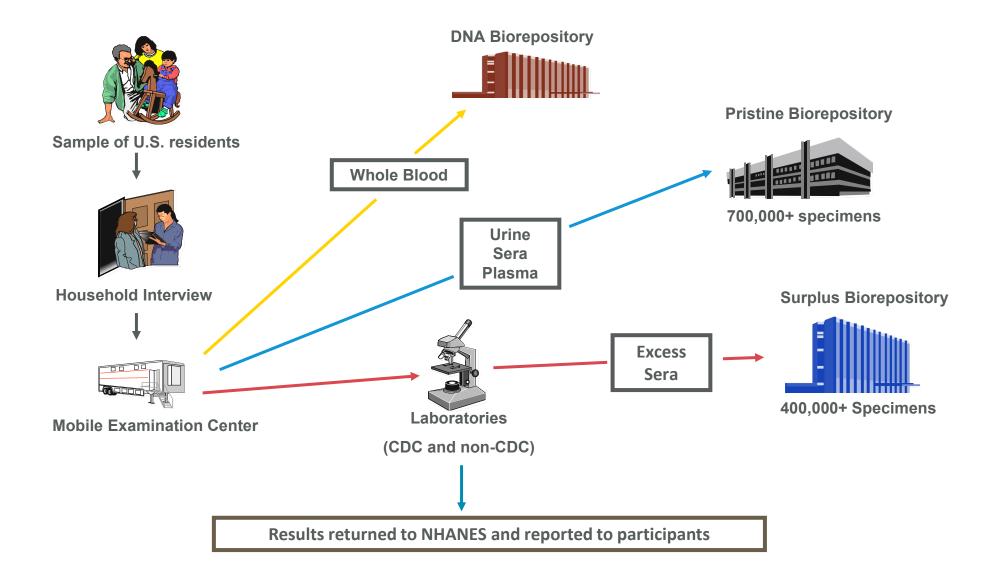
Prospectively, extends the life of the survey by providing resources for future research.

Retrospectively, allows for understanding of emerging infections and chemical exposures.



Overview

Mobile Examination Center to Biorepository





Biospecimen Program

- Sera, Plasma and Urine
 - Over 1 million samples available
 - NHANES III to present
 - Age 3+
- DNA
 - Available from 20,000+ participants
 - NHANES III, 1999-2002 and 2007-2012
 - Ages 20+
- An approved proposal is required to obtain samples
 - Over 135 proposals since 1993 for serum, plasma, urine specimens
 - Over 28 proposals since 2000 for DNA specimens



Proposal Process

Proposal Process

- Submit proposal to NHANES
- Scientific Review
 - -NHANES Project Officer
 - Technical Panel Scientific and technical merit
- Institutional Review
 - NCHS Human Subjects Contact
 - NCHS Confidentiality Officer
 - NCHS Research Ethics Review Board
- Distribute Specimens



Proposal Process - Caveat

 Only proposals with test results that are determined not to have clinical significance for participants will be accepted.

- One Clinical Significance Criterion
 - For serum, plasma, urine: Findings valid, done by CLIAcertified laboratory
 - For DNA: included as part American College of Medical Genetics and Genomics (ACMG) recommendations for reporting secondary findings.



Resulting Data

Resulting Data from Biospecimen Program

- Public Use
 - Available online with data documentation
- Limited Access
 - PII, indirect PII and sensitive data
 - Examples: genetic variants, geocoded, adolescents STI/STD
 - Available in the NCHS Research Data Center



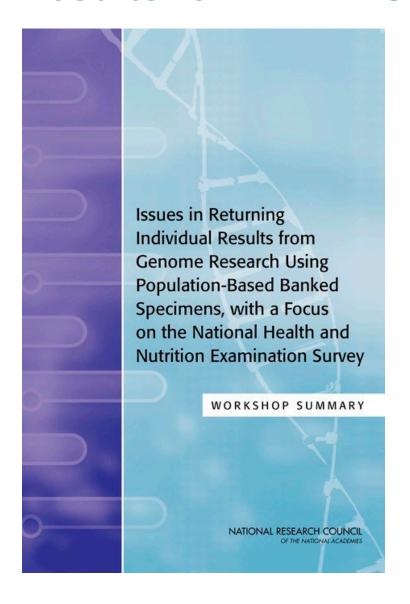
2014 Workshop: Issues in Returning Individual Results from Genome Research Using Population-Based Banked Specimens, with a Focus on the National Health and Nutrition **Examination Survey**

Statement of Task

How population surveys should address implementation of reporting of results from genomic research using **banked specimens**, identify options for reporting results and their advantages and challenges.



Results for NHANES



- In 2016 based on discussions from the previous workshop, NHANES provided new requirements for proposals using the DNA repository:
 - New DNA research could not generate clinically significant results, based on the most recent American College of Medical Genetics and Genomics (ACMG) recommendations
 - However, NHANES did not resolve the issue of informed consent and returning results for large-scale genetic testing during active data collection



Take away

NHANES is seeking to understand how to approach reporting of genomic results to participants.

NHANES is seeking to better understand how to address consent and return of results as we store DNA for future research.



NHANES Biospecimen Program Website:

https://www.cdc.gov/nchs/nhanes/biospecimens/biospecimens/s.htm

Thank you