National Health and Nutrition Examination Survey

Overview

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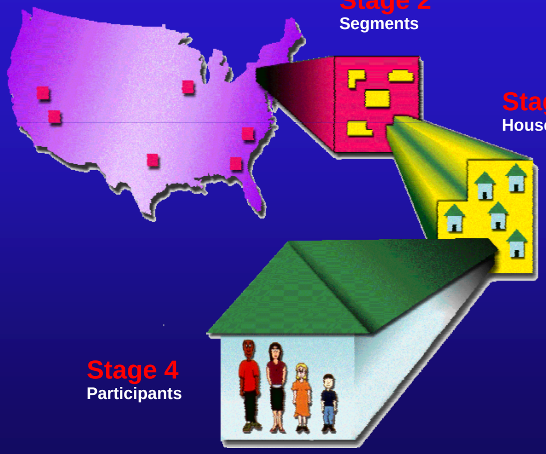
Goals of NHANES

- To assess the health and nutrition status of children and adults in the United States
- Create and maintain a nationally representative specimen bank

Overview

- NHANES is a cross-sectional survey of the U.S. household population
- Information is collected through:
    - In-person home interviews
    - Health examinations at mobile examination centers
- Annual sample size ~5,000
- No longitudinal follow-up



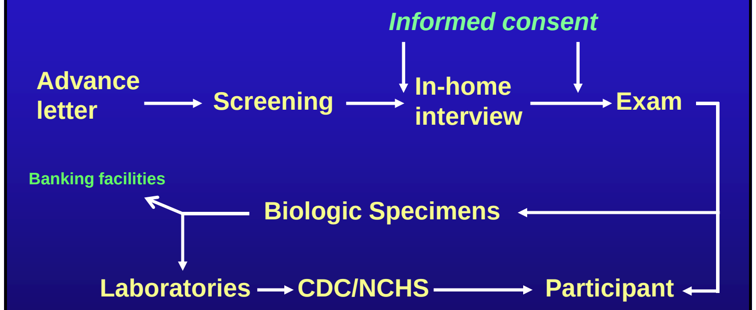
Stage 1
Counties

Stage 2
Segments

Stage 3
Households

Stage 4
Participants

NHANES information flow



Informed consent

Advance letter → Screening → In-home interview → Exam

Banking facilities

Biologic Specimens

Laboratories → CDC/NCHS → Participant

Consents

- Household interview consent
- Examination consent
- Consent to store blood and urine for non-genetic future research
  - Ages 3 and older (assent 7-17 yrs)
- Consent to store blood for future genetic research (ages 20+)

Non-genetic biospecimens

- Specimen bank created and opened to researchers in 1991
- Federal register notice on application process for researchers
  - http://www.cdc.gov/nchs/data/nhanes/Fed_Reg_Serum.pdf
- Proposals rejected if findings met the criteria for reporting back to participants
- Multiple levels of review
- DNA program modeled after this

NHANES consents - DNA

	Age	Separate DNA consent	Opt-out later	Notice of DNA studies	Plan to contact with results
1991-94	**12+**	**no**	**no**	**none**	_
99-02	**20+**	**yes**	**yes**	**Newsletter**	**no**
07-12	**20+**	**yes**	**yes**	**website**	**no**

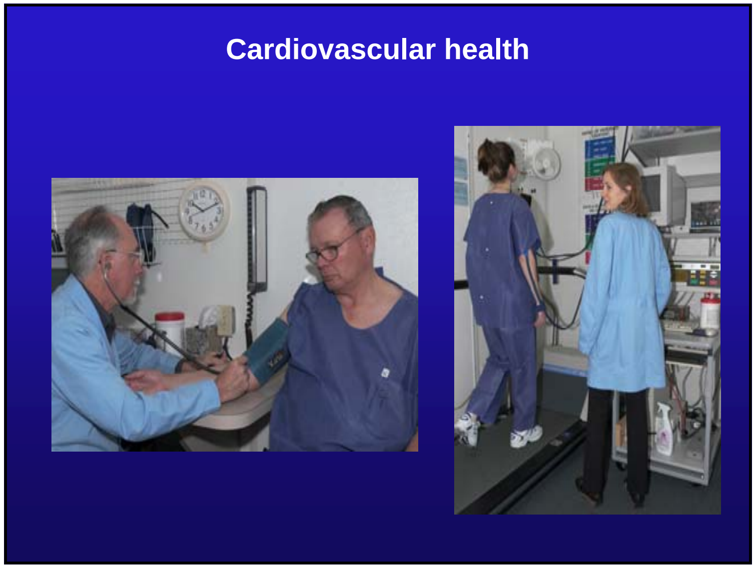
2013 – NHANES discontinued getting consent/banking DNA

NHANES home interview

NHANES mobile exam center

Mobile exam center entrance

Reception



Cardiovascular health

Hearing and vision

Anthropometry and body composition

Taste and smell

Oral health

Laboratory

Mobile exam center laboratory

- Complete blood count
- Pregnancy test
- Specimen processing
  - Blood, urine, water, swabs
  - 500 assays, 24 laboratories

Laboratory tests

- Nutritional biomarkers
- Hormone tests
- Diabetes
- Lipid profile
- Biochemistry profile
- Celiac disease
- Infectious diseases
  - Hepatitis viruses
  - Sexually transmitted infections
- Environmental Chemicals
- Water fluoride levels

Post exam assessments

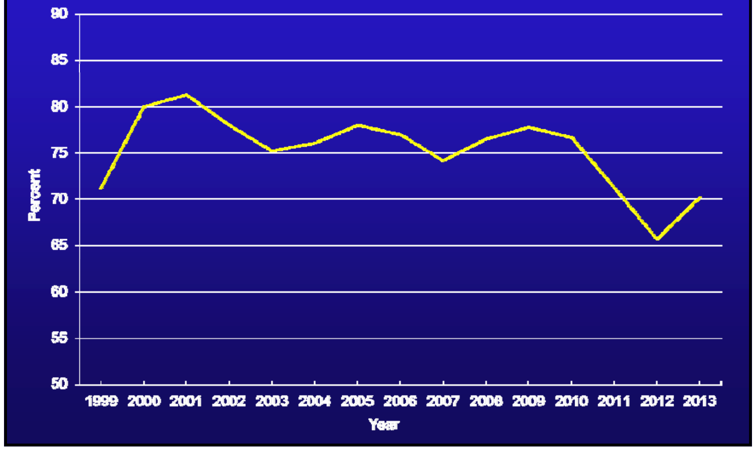
Day 2 Dietary Recall

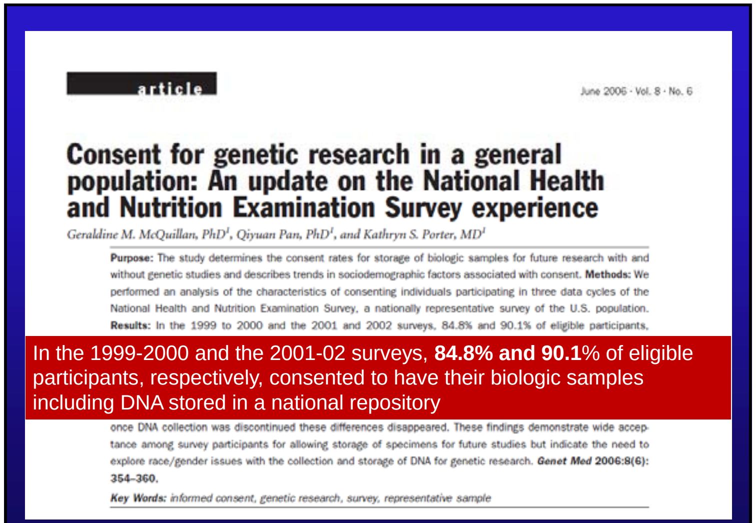
24-hour urine collection

Physical Activity Monitor

Home urine collection

NHANES exam response rates 1999-2013





article

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Consent for genetic research in a general population: An update on the National Health and Nutrition Examination Survey experience

Geraldine M. McQuillan, PhD[1], Qiyuan Pan, PhD[1], and Kathryn S. Porter, MD[1]

Purpose: The study determines the consent rates for storage of biologic samples for future research with and without genetic studies and describes trends in sociodemographic factors associated with consent. **Methods:** We performed an analysis of the characteristics of consenting individuals participating in three data cycles of the National Health and Nutrition Examination Survey, a nationally representative survey of the U.S. population. **Results:** In the 1999 to 2000 and the 2001 and 2002 surveys, 84.8% and 90.1% of eligible participants,

In the 1999-2000 and the 2001-02 surveys, **84.8% and 90.1**% of eligible participants, respectively, consented to have their biologic samples including DNA stored in a national repository

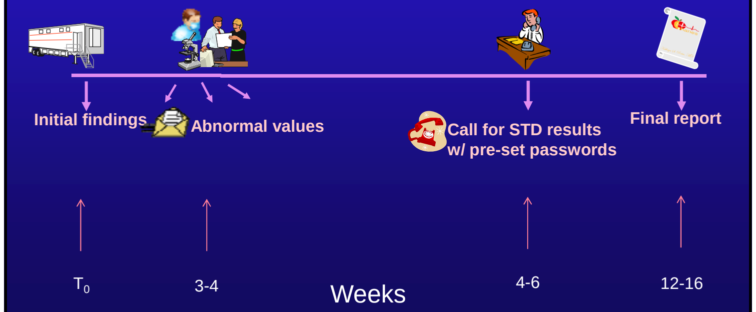
once DNA collection was discontinued these differences disappeared. These findings demonstrate wide acceptance among survey participants for allowing storage of specimens for future studies but indicate the need to explore race/gender issues with the collection and storage of DNA for genetic research. ***Genet Med*** **2006:8(6): 354–360.**

Key Words: *informed consent, genetic research, survey, representative sample*

Genet Med 2003:5(1):35–42

Do we give participants their results?

Yes



Initial findings

Abnormal values

Call for STD results w/ pre-set passwords

Final report

T_0

3-4

Weeks

4-6

12-16

Referrals

- Referrals are provided when necessary
- NHANES prepares lists of local clinics in advance of stand operations
- NHANES does not pay for any follow-up health care

What are the criteria for reporting a laboratory test result?

Criteria for reporting

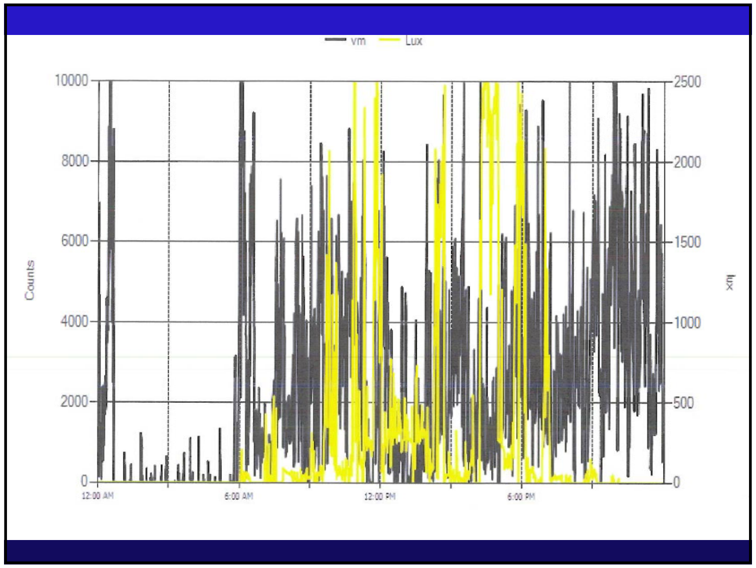
- The findings are valid and done by a CLIA-certified laboratory
- The findings may have significant implications for the subjects’ health concerns
- A course of action to ameliorate or treat the concerns is readily available

Can participants ask for test results that are not routinely reported?

Can participants ask for test results that are not routinely reported?

YES

Physical Activity Monitor



NHANES DNA Bank

NHANES DNA Bank

- Created in 1991
- Specimens available for use from:
  91-94: n = 5,948
  99-02: n = 7,839
  07-08: n = 4,611
  09-10: n = 3,898
  09-12: n ~ 3,800

Use of NHANES DNA Specimens

- Opened to researchers in 1999
- Proposal guidelines were on the web
- Proposals were received by NHANES staff
- Proposals were not allowed to move forward if research results met the criteria for reporting

Use of NHANES DNA Specimens

- Genetic Technical Panel review
- NCHS Research Ethics Board review
- Samples were released only after proposal was approved
- Great interest; 66 published papers to date

DNA bank closed to new proposals in 2012

Issue

- Genetic technologies evolved faster than our ability to manage research results
  1. Candidate genes
     - apriori knowledge of SNPs
  2. Genome wide association studies (GWAS)
     - Incidental findings – now what?
- NIH Bioethics consult 2009

[There is an increasing recognition among investigators, IRB members, and bioethicists that blanket non-disclosure of individual research results and/or incidental findings is inappropriate in public health research. However, much controversy exists about what findings should be disclosed, and how]

National Center for Health Statistics Workshop: Genetic Findings
May 2011

- One-day meeting
- Panel of experts
- What results should be reported back?
- Are there standards or guidelines available?

Binning the Genome

Bin 3 Genes of unknown clinical implication

Bin 2 Variants within genes that are clinically valid but not directly actionable

Bin 1 Variants within genes that have **direct clinical utility** based on professional organization diagnosis and treatment guidelines

Only Bin 1 variants should be considered for reporting

Berg. *Genetics in Medicine* (2011)

Getting it right

- NHANES Program developed procedures to report back to participants
- Approach was presented to the NCHS Board of Scientific Counselors, who suggested wider input on how the NHANES Program should proceed
- Issue for many population-based studies

Summary

- NHANES is a cross-sectional survey with limited, short-duration contact with participants
- The mobile examination center is not a clinical facility and no health care is provided
- Participants receive results from their health examination with recommendations for referral, if necessary
- Participants who agreed to have specimens stored for future genetic studies were informed they would not be contacted with individual results.

Thank you

nhanes