

# National Health and Nutrition Examination Survey

## DNA Bank Program

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# NHANES DNA Bank overview

- Created in 1991
- ~26,000 total specimens available for use from 1991-94, 1999-02, 2007-2012



# 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

\* Consent obtained to store blood for future testing, not DNA specific

2013 – NHANES discontinued collecting blood for DNA

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

Geraldine M. McQuillan, PhD<sup>1</sup>, Qiyuan Pan, PhD<sup>1</sup>, and Kathryn S. Porter, MD<sup>1</sup>

**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

# Use of NHANES DNA Specimens

- Opened to researchers in 1999
- DNA program modeled after NHANES biospecimens program (began in 1991)
  - Application process available in Federal register notice on web
  - Multiple levels of review
  - Proposals rejected if findings met criteria for reporting back to participants

# NHANES DNA research proposal review

- Genetic Technical Panel review
- NCHS Research Ethics Board review
- Samples were released only after proposal was approved
- DNA bank closed to new proposals in 2012

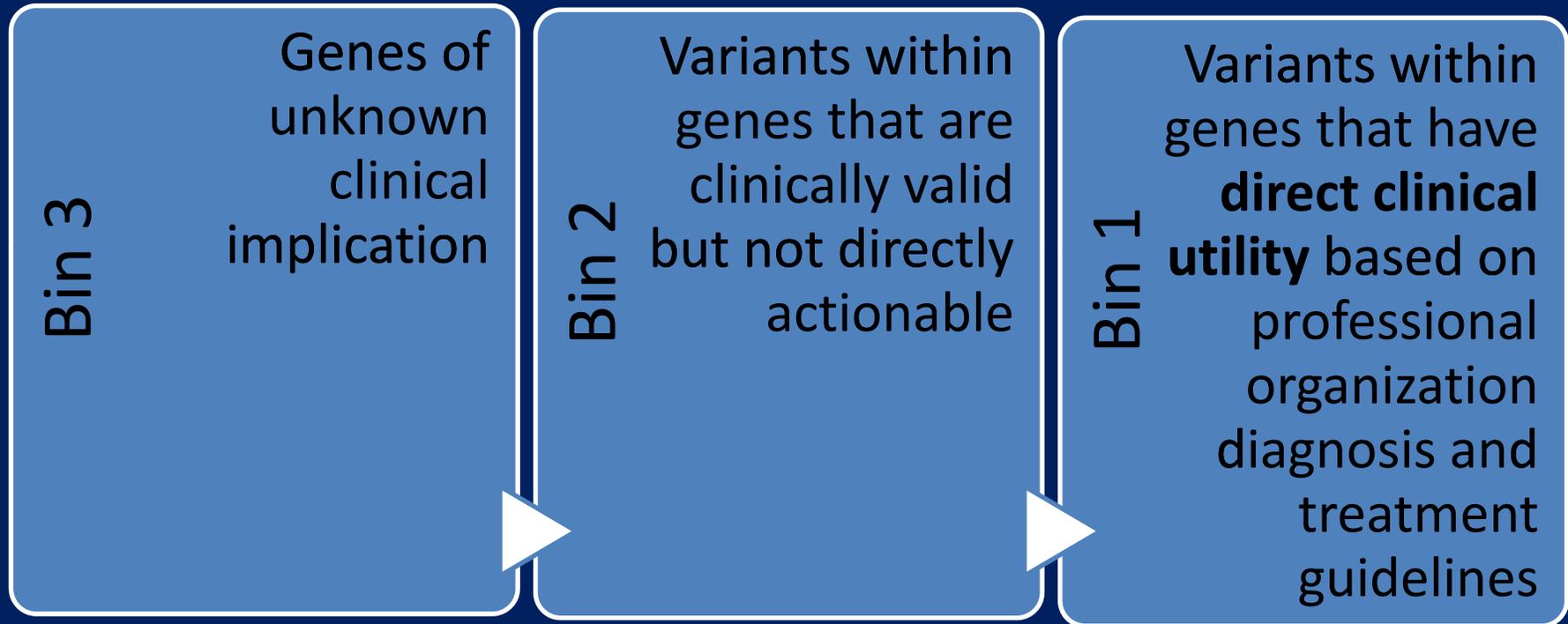
# Issue

- Genomic research has advanced
  - Cost of large scale genetic testing has declined
  - Research findings may potentially have clinical implications to respondent
- Technologies
  - Evolving faster than ability to manage research results
- Genome wide association studies (GWAS)
  - Concern about potential incidental findings

# NCHS 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



Only Bin 1 variants should be considered for reporting

# Getting it right

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

# National Academy of Science (NAS) Committee on National Statistics



- NCHS commissioned the NAS Committee on National Statistics to convene a workshop
- Purpose - to determine if and how NHANES and other population surveys with banked DNA specimens should return results from genetic studies
- Two-day workshop:

*Guidelines for Returning Individual Results from  
Genome Research Using Population-Based Banked  
Specimens*

# NAS Workshop – February 10-11, 2014

- Attendance onsite and remotely (*WebEx*) by ~ 100 persons
- Participants from the Federal government, universities, and private sector
- Participants from variety of specialty areas: research scientists, bioethicists, lawyers, epidemiologists, clinical geneticists
- Representatives from domestic and international population-based surveys

# Meeting agenda

## Day 1

- Overview of NHANES
- Perspectives on stringent or broad approach to returning results
- Evolution of genomic technology and ethical frameworks
- Comparison of NHANES with other population-based surveys
- Survey participants' attitudes
- Discussion on specific issues for NHANES
  - Scientific value of genomic data collection in NHANES
  - Discussion on what data are returnable

# Meeting agenda

## Day 2

- NCHS presentation
  - Logistics of returning genomic results
  - Special considerations as a statistical agency
- Summary and discussions

# Preliminary workshop outcomes

- Await NAS white paper of workshop outcomes
- In general, for *specimens obtained in the past*, issues raised did *not* support the need for NCHS to report results to participants
- In general, for *future DNA testing* many felt there is a need to report clinically actionable results

# NHANES next steps – *Retrospective specimens*

- Await full report from NAS
- Circulate NAS report to BSC or designees
- Receive BSC comments and reach final decision
- Reopen NHANES DNA bank

# NHANES next steps – Collecting DNA in future

- Plan full discussion with BSC at Fall meeting (after NAS report received and reviewed)
- Goal - to collect DNA from NHANES participants in future
- Issues to consider
  - Timing
  - Contact – how do we report?
  - Counseling
  - Consent – do we need pilot testing?
  - Community involvement

Thank you

