

## **Department of Health and Human Services**

### **Board of Scientific Counselors**

**October 29-30, 2014**

NCHS Auditorium  
3311 Toledo Road  
Hyattsville, MD 20782

### **Meeting Minutes**

The Board of Scientific Counselors was convened on October 29-30, 2014 at the National Center for Health Statistics in Hyattsville, MD. The meeting was open to the public.

#### **Committee Members**

##### **Present**

Raynard S. Kington, M.D., Ph.D., Chair BSC  
Wendy Baldwin, Ph.D.  
Virginia S. Cain, Ph.D., Executive Secretary  
Michael Davern, Ph.D.  
Mark Flotow, M.A.  
Hermann Habermann, Ph.D. (present Oct. 29; via phone Oct. 30)  
Christine L. Himes, Ph.D.  
Genevieve M. Kenney, Ph.D. (present Oct. 29; via phone Oct. 30)  
Thomas A. LaVeist, Ph.D. (Oct.29 only)  
F. Javier Nieto, M.D., M.P.H., Ph.D.  
Ana Diez Roux, M.D., Ph.D., M.P.H.  
Margo Schwab  
Linette T. Scott, M.D., M.P.H.  
Alan M. Zaslavsky, Ph.D. (via phone)  
Katherine K. Wallman, Ex-Officio, OMB (via phone)

## **MEETING SUMMARY** **October 29 - 30, 2014**

#### **ACTION STEPS**

- The next BSC meetings will take place on January 22-23, 2015 and May 21-22, 2015.
- The BSC will consider a revised plan permitting use of the existing NHANES DNA Bank. While some BSC members were concerned about the decision to disallow “actionable”

variants from genetic studies, the plan is consistent with earlier BSC discussions. The revised plan (which includes an elaboration of why analyses of “actionable” variants are not permitted) will be circulated to the BSC.

- An NCHS publication about sexual orientation recently listed in the New York Review of Books will be circulated to BSC members.
- A suggestion was made to consider the role of NCHS in the ICD-10 transition as a topic for the next BSC meeting.

*(Please refer to PowerPoint presentations for further specifics)*

## **Wednesday, October 29, 2014**

### **Welcome, Introductions and Call to Order**

Raynard Kington, M.D., Ph.D., Chair, BSC and Charlie Rothwell, Director, NCHS

### **NCHS Update**

Charlie Rothwell

NCHS published 65 articles in September 2014. Staff updates including retirements and new appointments were mentioned as were staff awards and accomplishments. NCHS’s response to Ebola was outlined. The 2015 budget was reported and program updates included DHIS; DHANES; DHCS; DVS; ORM; OAE; and Healthy People 2020. The Federal Interagency Forum on Child and Family Statistics was released in July 2014. A small grants program is being developed. The 16<sup>th</sup> annual Interchange between Statistics Canada and NCHS took place in November 2014 in Canada.

**Discussion** Discussion ensued about dealing with a problematic survey interviewer: the person is prohibited from further interviewing; and information gathered by that person is likely to be discounted. Census Bureau interviewer guidelines should be re-examined. Topics raised with Statistics Canada were identified (e.g., mobile examination centers; sexual identity; vital statistics; vital registration; social identification; sampling strategies). Improvements in mortality reporting were recognized.

### **NHIS Sample Redesign; 2016 NHIS Sample Allocation**

Chris Moriarity, Ph.D., Mathematical Statistician, DHIS

NHIS does sample redesigns approximately every ten years. The next redesign will occur in January 2016. Historic NHIS sample design features were identified; and the motivation for periodic NHIS sample redesigns explained, noting relatively minor changes in recent redesigns. In contrast, the 2016 NHIS redesign has several major changes, to include: more flexibility to increase or decrease overall sample and/or shift sample allocations by state from year to year; and a new source of sample addresses (e.g., one or more commercial address lists). Although the 2016 sample design will maintain some field listings, commercial address lists are slated to become the main sample address source.

Current NHIS sample redesign and year-to-year planning were described as were present and future milestones. Four 2016 sample options were presented. Option #2 has been chosen because it enables three-year estimates for Washington D.C. and all 50 states (~ 21 states per year) with only a slight loss of national precision. This option modifies Option #1 by reducing samples in the 40 most populous states and increasing samples in the ten least populous states and Washington D.C. to approximately 250 completed household interviews.

**Discussion** The commercial list to be used in the 2016 sample redesign has not yet been announced. To date, the Census Bureau has been authorized to share a limited amount of information with NHIS. As further review is needed, it is not clear when NHIS will be allowed to release information to the public.

MSG (source of the delivery sequence file) uses a combination of sources for their commercial list that probably changes over time, including an indirect interaction with the USPS delivery sequence file that is not for sale on the open market. Efforts are being made to explore available options for accessing the postal service sequencing file across federal agencies. Movement forward is with independent listing although an assessment of information from listers is planned, especially in areas where vendor lists have specific addresses that can be linked to records. Master address files of the Census Bureau and NCHS must be equivalent. One fundamental difference is that NHIS efforts, limited to NHIS sample areas, are more limited in scope. NHIS must accurately represent smaller groups within the national perspective and when possible, add additional states. The current projection is two or three years in a row of 50+ one-state estimates, measured according to an estimate of the healthcare coverage rate for all ages. National estimates for FY 2014 provide a good base although more could be done with additional funding.

### **NHANES DNA Bank – NAS Report and Next Steps**

Kathryn Porter, M.D., M.S., Director  
Susan Lukacs, D.O. M.S.P.H., Science Advisor  
Jody McLean, M.P.H., Geneticist, DHANES

An overview was presented to include: the current status of the NHANES Genetic Program; innovations (e.g., improving researchers' access to genetic variables); a summary of the NAS Workshop, "Issues in Returning Individual Results from Genome Research Using Population-based Banked Specimens (February 2014) with a focus on the NHANES survey; and plans for reopening a DNA bank. Genetic data have great value in assessing health using genomic lab tests rather than health measurements (soda drinkers example given).

Ms. McLean presented her team's final winning HHS Ignite talk, the objective of which was to encourage research at the intersection of genetics and public health. The team proposed replacing the PDF list of genetic variables with a searchable database (example given to illustrate database use). The database prioritizes content over web interface. The team is working on a prototype with plans to post available NHANES data in a searchable database within months; and add the 500-fold increase of genetic variables in 2015. This tool will save researchers a great deal of time.

Current discussions are underway about reopening the DNA Bank for people who have already given consent. One principle derived from the NAS Workshop mandates that no individual participants be contacted or receive test results. NHANES genetic studies are categorized as research intended to create generalizable knowledge. In addition, concerns were raised about

the work done in non-Clinical Laboratory Improvement Act (CLIA) certified labs. A plan was presented for making NHANES available to researchers, noting that only proposals testing for variants not clinically actionable may be submitted. “Clinically actionable” was defined in accordance with an article published by The American College of Medical Genetics and Genomics (July 2013) entitled, “The ACMG Recommendations for Reporting Incidental Findings in Clinical Exome and Genome Sequencing”, which identifies 56 genes and clinical variants that should be reported to participants. A working group has made recommendations about responsible management of these findings that have been approved by the ACMG Board.

The NCHS RDC process was outlined as were next steps, which include: seeking endorsement from NCHS BSC; submitting the document about a new protocol, “Plan for Making Banked NHANES DNA available for Genetic Research” for review and approval; and opening the DNA Bank to researchers.

**Discussion** The NAS Workshop was further described, noting that no consensus was reached nor official recommendations made. The workshop did not include much discussion on the ethics of telling people that they would not receive individual results; and differing opinions were presented. The terms “clinically actionable” and “actionable” are still “unsettled law”. The question is where to go from here given how quickly things are changing. A clear rationale for why actionable genetic tests are not acceptable is needed for the draft protocol document as is background information.

Is it paternalistic to control the research by not allowing clinically actionable tests to be done? A tension exists between research done in clinical settings (where the rule is to let patients know their results if enough data are gathered) and research settings (where participants are not told of their results). There is no right or wrong answer. Further discussion is warranted with regard to what is relevant; as is the need to address inevitable changes (e.g., something not actionable that becomes actionable over time).

NHANES’s historically consistent approach includes a report of the survey design as well as clinically important results of all tests. Not taking the same approach with genetics would be inconsistent, despite greater complexities (i.e., genetics apply to families and are forever). Further complications arise when considering whether to contact participating individuals when the research yields new information in the future (e.g., surplus serum example). If the meaning of an environmental test becomes clear in five years, it would not be reasonable to contact past participants.

The complexities of defining “actionable” (particularly in genetics) were reiterated. Are genetic risk scores actionable? Not allowing people to see results because researchers don’t want them to raises ethical concerns. What do researchers do when they decide that they won’t examine anything actionable but then discover that what they have is actionable? In today’s world, there is no longer a gene-by-gene approach: rather, there is genotyping with millions of markers that can be used by many people for different things, including the identification of clinically actionable genes. Will the DNA be given to lots of different groups for genotyping or will it pass through big consortia for analysis?

While there are no plans for a prospective protocol, the hope is to one day include whole genome sequencing as part of the live current survey. The question of suppressing scientific inquiry was raised. The NHANES Genetics Technical Panel will participate in developing guidelines to help researchers understand how inquiries are evaluated. Reporting back is an ongoing but pressing issue.

Why not address the ethical dilemmas and allow scientific inquiry to move forward? This might be possible if the process were not connected to the NHANES protocol and standard. The live survey has reporting criteria. Again, because genetics are forever, reporting back issues of concern becomes much more important. The purpose of reopening the DNA Bank to stored samples was questioned.

With all the complexities and differing opinions, what are the next steps? One must be careful not to overstate the utility of genetic information. Discussion followed about the consent form; options offered to research participants; and the RDC review process. Researchers are more interested in looking across populations than at diseases that affect small portions of the population. It should be understood that only a very small proportion of proposals with clinically actionable data will be excluded. Better guidelines will be developed. However, the process does not allow for whole genome sequencing. Will clear criteria be developed to help the IRB determine whether a proposal should move forward? The need to differentiate research and clinical goals was stressed.

Discussion ensued about what happens when a 57<sup>th</sup> gene is identified. The idea is to move forward, noting that when the list of 56 genes grows, the data must go through a disclosure process. Data about the 57<sup>th</sup> and other genes identified in the future will be treated the same as the first 56.

What is the BSC's role relative to next steps? Initially, the BSC had sought broader input on their 2011 plan. Themes from the NAS Workshop have been written into a new plan. The BSC will consider a revised plan permitting use of the existing NHANES DNA Bank. While some BSC members were concerned about the decision to disallow "actionable" variants from genetic studies, the plan is consistent with earlier BSC discussions. The revised plan (which includes an elaboration of why analyses of "actionable" variants are not permitted) will be circulated to the BSC. The document will go to the IRB while the public will have access to a federal register notice. As an IRB document, it will modify the protocol. To summarize, the BSC believes the plan to be a reasonable approach consistent with BSC discussions despite no consensus.

### **NHIS Health Insurance Estimates; NCHS/Census Pre-release Outreach**

Jennifer Madans, Ph.D., Associate Director for Science, NCHS

The first 2014 insurance data is of particular interest because it was the first federal release of information following ACA implementation (covering January – March 2014, the last three months of open enrollment). The release, which went very well, led to collaboration between NCHS and the Census Bureau in an attempt to promote transparency and awareness of upcoming releases in relation to methodology and analysis of the two different surveys. An August 2014 event planned to promote such collaboration was described along with its agenda and audience. At the event, CPS focused on changes in insurance data collection while NCHS addressed NHIS activities. The NHIS Early Release (ER) Program was delineated as were the contents of the Health Insurance ER Report and release dates of the ER health insurance estimates through December 2014 (noting additional access to preliminary microdata files via NCHS's RDC).

**Discussion** None.

## **Collection and Classification of Health Insurance through the Marketplace/Exchanges; 2014 First Quarter Estimates**

Robin A. Cohen, Ph.D., DHIS

A historical perspective of NHIS health insurance content since 1959 was provided as was the general approach to NHIS insurance content since 1997 (examples given). The presentation included a synopsis of the following areas: evaluation and coding of coverage source; health insurance plan coding; resulting classification of current coverage; confusion about whether exchange coverage is public or private; coverage obtained through the Health Insurance Marketplace or state-based Exchanges (new for 2014); and method for determining Exchange coverage. It was noted that Exchange coverage would be assigned if certain criteria are met (examples given). The method for determining Exchange coverage includes all individuals classified as having private health insurance, regardless of whether coverage has come from a private or public source.

First quarter 2014 DHIS estimates were reviewed, including: early release of health insurance estimates; percentage of those lacking health insurance coverage at the time of the interview by age group; the millions without health insurance coverage at the time of interview by age group; and percentages with and without health insurance coverage at the time of interview by age group from 2013 - March 2014. Estimates by selected demographics were also presented for the same timeframe of adults age 18-64 by poverty status; race/ethnicity; by state Medicaid expansion status; and by state health insurance marketplace type. Private coverage by type of plan was also described as was a comparison of the prevalence of uninsured persons from the NHIS and CPS by survey data source, age group and race/ethnicity from January - April 2014.

**Discussion** DHIS is the first federal survey to attempt the identification of marketplace enrollees separately. It is hoped that such information will be available to researchers. Because most people provide the name of their health insurance company rather than that of their plan, the resulting ambiguity would benefit from sensitivity analysis. States make different decisions about who provides Exchange coverage. Because most states have no intersection between private and public providers, most Exchange plans only deal with private coverage (with the exception of CA and NY). Developing algorithms and decision rules about Exchanges has been complicated.

CPS's capacity to reclassify is more limited than that of DHIS. For example, CPS only collects health plan names if people haven't classified their coverage as private or Medicaid whereas DHIS collects health plan names from every type of coverage. The two departments ask questions differently. CPS noted a huge change in the percent of uninsured (5.6 percentage points) while DHIS had not yet captured that surge. Generally, however, CPS and DHIS numbers are similar despite different data collection although two areas that differ significantly are children and older adults. It was suggested that DHIS is a better source of insurance data than CPS.

The December 2014 DHIS information release during the open enrollment period will be followed by a March 2015 release. The integrity of these releases matter, particularly due to concern about their high political profile. It is important for people to understand the numbers relative to when data are released. In response to a question about the survey's ability to distinguish Plan quality, it was clarified that the NHIS is not designed to assess the quality of private plans. An increase in high-deductible Health Plans was noted, especially among employment-based Plans. Emergency room visits data (tracked in 2011 and in 2012 for children) will be updated. It is premature to count on data estimates affected by delayed

reporting (example given of a temporary increase of ED visits in CA with the switch by many from fee-for-service to managed care before a drop in numbers occurred).

## **Thursday, October 30, 2014**

### **Welcome and Call to Order**

Raynard Kington, M.D., Ph.D., Chair, BSC

### **OAE Clinton Foundation Webinar**

Julia Holmes, Ph.D., Branch Chief, Analytic Studies Branch

James Craver, M.A., Assistant Director, OAE

An outline of a Webinar on national health trends given by the “Health United States” team to the locally-based, five-state *Clinton Health Matters Initiative* was presented, to include an introduction to the congressionally-mandated “Health United States” report including its use and substance. The *Clinton Initiative* works in organizations and communities to promote healthy behavior; and to reduce the prevalence of chronic disease, disparity between groups and the burden of illness. Content examples from the report (known as the “gold standard” for public reporting on the health of the nation) examined indicators of mortality; reproductive health; behavioral risk factors; and healthcare utilization (tables, graphs and examples illustrated points). Also described and illustrated was the Health Indicators Warehouse (HIW), a query-based internet system that accesses many indicators at national and state levels, especially for mortality and natality (demonstration example given of how to use the Warehouse data within Arkansas). The data are free, open to the public, pre-aggregated and pre-tabulated such that suppression concerns are addressed upfront. Developers are required to have an API key for tracking purposes.

**Discussion** There are fewer HIW general than targeted users (less than 10,000). Several dozen people are application programming interface (API) users. While several good test application examples exist, most were developed by individuals who don’t have incentives to update or revise what they’ve created. HIW has not yet worked directly with Code for America. A suggestion was made to ask the Clinton Foundation or others to sponsor code-a-thon competitions. HIW has presented at every *Health Datapalooza* since they began around four years ago; and has also participated in some Code-a-thons. This is a good time to re-engage with that community and become involved with the challenge.gov site.

Over half of the HIW indicators are sourced from the *Healthy People* Program, including the breakdowns for race/ethnicity. Another source is “Health United States”. Breaking down HIS data is dependent upon the data set itself. The advantage of the Warehouse is that the data are collected in one place and available through an API. The Community Health Status Indicators and County Health Rankings and Roadmap Project define “community” for the HIW, which examines data from the national data collection perspective rather than from the ground up.

Many states with a high number of opioid drug-poisoning deaths also have a high number of drug-poisoning deaths. While there are variations by state, overall patterns prevail. How age ranges are chosen to delineate child versus adult status (with regard to obesity, for example) has to do with a decision made years ago by NHANES about their sampling strata.

The front page of the NCHS website shows all data activities and links into its data access systems and specific surveys. A suggestion was made to have “Health United States” become the front page to indicate NCHS’s role and to immediately engage users with major issues of morbidity and mortality as well as healthcare provisions. This might interest more of the general public but not appeal as much to researchers.

The presentation about “Health United States” was requested by the Clinton Foundation in support of their use of data to anchor interventions as benchmarking tools. Where else might the presentation be useful? Suggestions included: outreach to the Robert Wood Johnson Foundation’s *Culture of Health* Initiative; piggybacking with the IOM report about the United States health disadvantage; creating a “Health United States” road show for communities across the country; preparing presentations for every state; hosting webinars; partnering with others (e.g. state departments; universities) to host such presentations; and using the presentation as a graduate training tool. Would foundations fund the continued and updated use of this valuable resource for use in all 50 states? This tool can also help non-profits consider where to target resources relative to the IRS community benefits requirement (Hilltop Institute’s work with community benefits referenced).

### **ORM One-Year Update**

Nathaniel Schenker, Ph.D., Director, ORM

A main theme of the BSC review was ORM’s collaboration with other NCHS programs. ORM has increased focus on such collaborations (examples include SRSDS; QDRL and RDC). ORM has some “reverse dual citizenships” (examples given within RDC and the Planned QDRL Detail Program). A new “Ask the Methodologist” program includes seminars and an expert visitor series. Examples of collaborative work were presented, including awards received by ORM and other divisions for collaborative work (e.g., 2013 & 2014 NCHS Director’s Awards; CDC Honor Award nominations; articles receiving CDC/ATSDR Statistical Science Awards); and a host of other workgroups, committees and projects. The Q-Suite of QDRL was delineated.

Hiring and staff development were reviewed as were communication strategies, successes, challenges and dissemination efforts. Outreach outside of NCHS was discussed along with cross-staff collaboration within ORM. Considerations for the future include: reorganizing ORM into three units; establishing priorities for research, training and hiring; gathering big data and non-probability samples; addressing questions about ORM’s role in dissemination; and determining the RDC role in NHIS’s On-line Analytic Real-time System (OARS).

**Discussion** While part of ORM’s strategic plan relates to the BSC process, there is no formal strategic planning process at present. Questions were posed about difficulties in selling or promoting use of new statistical methodology across the Center; and whether a chasm exists between theoretical methodological staff and data producers. While there is some resistance to new methodology outside of ORM, it diminishes with practice (rather than just theory) and good results (example given of how new multiple imputation procedures for income were introduced when working with DHIS). Small area estimation is an important consideration in ORM. An agreement with the Census Bureau has been reached to use small-area data from the ACS. ORM is also working with DHIS on wireless substitution rates and NHIS data estimates. Another project addresses how to triage variables.

## **Sexual Identity Report**

Jim Dahlhamer, Ph.D., Senior Specialist in Survey Methods, DHIS

The presentation reported sexual orientation results from the NHIS, including: a summary of the final NHIS field test of sexual orientation question; use of audio computer-assisted self interviewing (ACASI); initial results from the 2013 NHIS, in which the question went live for the first time; and past, present and future research efforts. Three constructs of the sexual orientation issue are behavior; attraction; and identity.

A summary of goals, plans, procedures and results of the final field test were delineated as were initial results of the 2013 NHIS (i.e., sexual orientation response distribution; sexual orientation among U.S. adults age 18 and over by sex and race/ethnicity and by education and age group). Health behavior indicators (such as cigarette smoking and aerobic physical activity by sexual orientation and sex for adults 18-64 years) were illustrated in graph form as were health status indicators; healthcare service and utilization indicators; and healthcare access indicators. Publications and research were described.

**Discussion** More data are needed about the shifting landscape of marriage and spousal benefits that relate to health insurance. The use of ACASI was discussed. The shift in data mode collection for sensitive questions has been played down. In some instances, sensitive questions have been embedded within other less threatening questions. Switching to ACASI has sometimes become an excuse for interviewees to terminate interviews before completion. The presenter believes that the sexual orientation question is better placed in the CAPI than in the ACASI. No increased break-off has been noted and nothing has changed with the addition of the question. A module has been developed and successfully integrated into the instrument.

Although comparative analysis with the National Survey of Family Growth (NSFG) shows two very different contexts for the questions when asked by NHIS and NSFG, the patterns of health outcomes by sexual orientation are very consistent. Estimates of “gay” and “lesbian” are very close while NHIS estimates for bisexual are a percentage point lower. One hypothesis is that these results have something to do with the order in which questions are asked relative to attraction, and behavior. Another noted slightly different questions (and wording) in the NHIS and NSFG surveys; and misclassification as possible contributing factors to the gap. There were few problems with translation in the second field test.

It was noted that the New York Review of Books recently listed an NCHS publication about sexual orientation, which will be circulated to BSC members.

**PUBLIC COMMENT**           None.

## **BSC Wrap-Up**

Raynard Kington, M.D., Ph.D. and Virginia Cain, Ph.D.

**Discussion** ICD-10 is planned for 2015. A presentation at a 2014 AHIMA meeting about the comparability ratio of measures between ICD-9 and ICD-10 derived its analysis from a paper about death certificates published in 2001 in the National Vital Statistics Reports. The upcoming shift to ICD-10 offers an opportunity to revisit the thinking and improve



## **ATTENDENCE**

### **Presenters**

#### October 29, 2014

Robin A. Cohen, Ph.D.  
Chris Moriarity, Ph.D.  
Susan Lukacs, D.O., M.S.P.H.  
Jennifer Madans, Ph.D.  
Jody McLean, M.P.H.  
Kathryn Porter, M.D., M.S.  
Charles Rothwell, NCHS

#### October 30, 2014

James Craver, M.A.  
Jim Dahlhamer, Ph.D.  
Julia Holmes, Ph.D.  
Nathaniel Schenker, ORM, NCHS Staff

### **Others**

#### October 29, 2014

Irma Arispe, Ph.D., OAE  
Lisa Banana, DHIS  
Stephen Blumberg, DHIS  
Clarice Brown, M.S., DHCS  
Mary Ann Bush, OAE  
Pei-Lu Chin, DHIS  
Juanita Chinn, OCD  
Traci Cook, OPBL  
Luis Cortes, ORM  
Sandra Decker, OAE  
Adena Galinsky, DHIS  
Jane Gentleman, Ph.D. DHIS  
Renee Gindi, OPBL  
LaJeana Hawkins, OAE  
Debbie Jackson, NCHS  
Dean Judson, OAE  
Hashini Khajuria, OAE  
Hannah Lawmen, DHANES  
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Xianfen Li, CDC/NCHS/OAE  
Patsy Lloyd, OAE  
Donald Maloc, ORM  
Peter Meyer, ORM  
Jennifer Madans, Ph.D., NCHS  
Hanyu Ni, CDC/NCHS/DVS  
Jim Nowicki, CDC  
Colleen Nugent, DHIS  
Jennifer Parker, OAE  
Van Parsons, ORM  
Charles Rothwell, NCHS  
Nathaniel Schenker, ORM

Angela Sharpe, Consortium of Social  
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Suresh Srinivasan, CDC/NCHS/DHIS  
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Rashmi Tandon, OAE  
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Ritu Tuteja, OAE  
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Robin Wagner, CDC/OPHSS  
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#### October 30, 2014

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