Department of Health and Human Services

Board of Scientific Counselors

September 22-23, 2011

NCHS Auditorium
3311 Toledo Road
Hyattsville, MD 20782

Meeting Minutes

The Board of Scientific Counselors convened on September 22-23, 2011 at the National Center for Health Statistics in Hyattsville, MD. The meeting was open to the public.

Committee Members

Ronald J. Angel, Ph.D.
Patricia Buffler, Ph.D., M.P.H. (by phone)
Llewellyn Cornelius, Ph.D., Chair BSC
Hermann Habermann, Ph.D.
Carol J. Hogue, Ph.D., M.P.H.
Holly Hedegaard, M.D.
Michael J. O'Grady, Ph.D.
Stanley Presser, Ph.D.
Elizabeth (Lou) Saadi, Ph.D.
Margo Schwab, Ph.D. for Katherine K. Wallman
Duncan Thomas, Ph.D.
Alan M. Zaslavsky, Ph.D.

Absent

José Escarce, M.D., Ph.D.
Kathleen Mullan Harris, Ph.D.
David Takeuchi, Ph.D.
Katherine K. Wallman, Ex Officio Member

Staff and Liaisons

Virginia S. Cain, Ph.D., Executive Secretary
Jennifer Madans, Ph.D., NCHS
Edward Sondik, Ph.D., Director, NCHS

Presenters

September 22, 2011

Virginia S. Cain, Ph.D., Designated Federal Official
Llewellyn Cornelius, Ph.D., Chair, BSC
Marcie Cynamon, M.A., Division of Health Interview Statistics
Rosemarie Hirsch, M.D., M.P.H., Division of Health and Nutrition Examination Surveys
Marian F. MacDorman, Ph.D., Division of Vital Statistics
Jeannine Schiller, M.P.H., Division of Health Interview Statistics
Edward Sondik, Ph.D., Director, NCHS

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Clarice Brown, M.S., Division of Health Care Statistics
Virginia S. Cain, Ph.D., Office of the Center Director
Robin Cohen, Ph.D., Division of Health Interview Statistics
Peter Meyer, M.P.H., Research Data Center, Office or Research and Methodology
Christopher Moriarity, Ph.D., Division of Health Interview Statistics

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ACTIONS

- A subset of BSC members will participate in a conference call before the next BSC meeting to discuss next steps for advising NCHS about questions concerning report of genetic results from the NHANES program. The result of this call will be reported back to BSC members.

- BSC members are reminded to let Dr. Cornelius or Dr. Cain know if they plan to attend the interchange by October 30, 2011.

- BSC members are asked to send to Dr. Cornelius or Dr. Cain ideas about the 15 health measures in the early data release program.

- Dr. Cornelius and Dr. Cain will develop logistics for an interface with the NHANES DNA Workgroup.

- NCHS will circulate to BSC members an article from *Genetics in Medicine*: June 2011 - Volume 13 - Issue 6 - pp 499-504 Deploying Whole Genome Sequencing in Clinical Practice and Public Health: Meeting the Challenge One Bin at a Time; Berg, Jonathan S. M.D., Ph.D.; Khoury, Muin J. M.D., Ph.D.; Evans, James P. M.D., Ph.D.

Thursday, September 22, 2011

Welcome and Call to Order **Virginia S. Cain, Ph.D., Office of the Center Director**

Understanding Racial and Ethnic Disparities in U.S. Infant Mortality Rates
Marian F. MacDorman, Ph.D. Division of Vital Statistics

Based on NCHS's linked birth and infant death dataset, the *Understanding Racial and Ethnic Disparities in U.S. Infant Mortality Rates* brief co-authored by Marian MacDorman, Ph.D., and T. J. Mathews, M.S. (2011) provides more accurate and detailed information about U.S. infant mortality. Pertinent facts about U.S. ranking in infant mortality were presented as was the steady increase of preterm births and its influence on mortality rates (1985-2006). U.S. rates have since improved but are still considered to be very high (refer to *CDC Health Disparities and Inequalities Report, U.S. 2011*, MMWR Supplement/Vol.60, January 14, 2011). Race and ethnic disparities in infant mortality constitute one of the largest disparities in health research (examples given). Two key components of overall infant mortality rates (gestational age-specific infant mortality rates and the distribution of birth by gestational age) were delineated relative to specific ethnic groups. The findings are consistent with the cause of death analysis. Comparisons of infant mortality rates for non-Hispanic black women, non-Hispanic white women and American Indian women were made, noting different causes of death within different ethnic groups. These patterns suggest different prevention strategies. Not all racial and ethnic groups have benefited equally from social and medical advances.

Discussion Differences in congenital malformation infant mortality were delineated between races and over time. With ongoing questions about why even well-educated African American women with access to healthcare have trouble with preterm birth and infant mortality, a suggestion was made to examine black women with positive birth outcomes to determine what they are doing right. NCHS may examine geography and state-by-state differences from linked data in the future. Further specifics about the data of American Indian women were requested. International differences were discussed with references to a 2009 NCHS data brief. A suggestion was made to use multivariate approaches and analysis to illustrate different controlling variables in order to be useful in policy decision-making. An integrated presentation was recommended (rather than separating out socioeconomic or racial factors).

NCHS data briefs strive to be short and simple. Although a statistical report, the longer National Vital Statistics Report contains tables and multivariate analyses. More analytic reports are published in journals. NCHS strives to achieve the proper balance between these reporting forms; and the importance of the target audience was recognized. Within the MMWR, the shorter Quick Stats report was described. The briefs have been well-received by the public, the media and Congress. Within the U.S., late fetal death now comprise about half of all deaths of viable fetuses, although fetal deaths are the smallest dataset when examining infant deaths. A methodologically rigorous report for policymakers was recommended.

NCHS Update **Edward Sondik, Ph.D.**

The specifics of NCHS's budget for FY2011 were delineated. A suggestion was made to notify partners in the data collection effort of a need for ongoing support in order to maintain data levels, in concert with the CDC Foundation. Much of what is slated for 2012 will be paid from

2011 funding. Program highlights were presented. Features of NCHS's website were described, to include *What's New*; *New Releases*; and *NCHS Data Briefs*. C-SPAN is featuring the federal statistical agencies weekly for a year in a "folksy" and accessible manner. Public concerns in response to the show are primarily about longevity. The place of social media for informing the general public about health statistics was discussed, noting that CDC has developed sophisticated ways to use these tools.

Other collaborations (between NCHS and SAMHSA in 2013 and with the Department of Agriculture in NHANES) were described. NCHS is also working on an earlier release of data. Two surveys about EHR adoption are underway (specifics given). Health Interview Statistics has produced *American's Children Report* with an adoption feature. HIS is also testing demographic questions for lesbian, gay and bisexual data collection. OAE will release linked Medicaid files in October 2011. The Department will also release the 2010 Final Review of *Healthy People 2010* in September, with a webinar on October 6, 2011. Research and development in NHANES is associated with the National Health and Nutrition Examination Survey. Prestigious staff awards were recognized. In Vital Statistics, the Secretary approved moving forward with minimum standards for birth certificates (draft set of standards).

NCHS BSC Working Groups

Lee Cornelius, Ph.D. and Virginia S. Cain, Ph.D., Designated Federal Official

Issues to consider include continuity of BSC activities (e.g., user accessibility for the Research Data Center); and ways that BSC can support the Center formally and informally. Dr. Cain described workgroups and subcommittee mechanisms. The two mechanisms available to Federal Advisory Committees (subcommittees and workgroups) were delineated. Subcommittees can examine and articulate specific issues for the BSC more efficiently than can the group at large within the confines of a meeting. However, the recommendation is to move toward more informal workgroups, which remain the best option for review of individual surveys and individual programs. BSC workgroups would make recommendations to the BSC rather than directly to NCHS. Currently, the NHANES DNA Program cannot move forward because of challenges from the Ethics Review Board. Dr. Cain suggested that the BSC establish a workgroup to address these concerns that could serve as a model for other workgroups. Because a big challenge has to do with how to determine the process, the discussion began with how, in general, workgroups might function. Workgroups make recommendations, rather than independent decisions, to parent committees. As an advisory committee, the BSC's function is strategic. The benefits of the Board's informal discussions were noted. The possibility of webinars was raised.

NHANES DNA Update and BSC Working Group

Rosemarie Hirsch, M.D., M.P.H. Division of Health and Nutrition Examination Surveys

Prior to Dr. Hirsch's presentation, Dr. Madans provided a brief history of DNA as part of NHANES. The past challenge with DNA has been to maintain data confidentiality while keeping information available and accessible to researchers. Now, there is a new challenge with big implications that has to do with report of findings (linked to consent and stored specimens) and ethical considerations (refer to presentation).

NHANES DNA analysis was described as was the process of gathering and using NHANES DNA specimens. Also summarized were ethical issues and the genetics consent form; advances in genetics research and guidance; and a step-by-step breakdown of reported finding issues. NHANES protocol issues were delineated. Genetic technology advances and new

analysis techniques have increased the potential for identifying incidental clinically relevant findings. The main issue has become report of findings. Specifics of the consent form and what information is available to participants were discussed. The issue of retesting on stored specimens may be revisited for the sake of future advancement.

Background on the contribution of genetics to the evolution of the NHANES program was provided. With regard to ethics changes, a 'no reporting back' policy has evolved into 'right to know' and 'right not to know' due to advances in genetics. With technology changes, the possibility of incidental findings with clinical relevance to participants has increased, which affects more than NHANES (e.g., including the genetics research community). The 2003 candidate gene proposal process was delineated. A suggestion was made to avoid clinically relevant studies; set a high bar for disclosure results; and consider developing a policy for addressing potential future notification). The 2009 GWAS proposal and process were described relative to approach, solicitation, analysis protocol, benefits to participants and testing. Implementation challenges and questions (2010) were identified. A dire duty to warn threshold should be the only one that requires individual subject re-contact. But, how should "dire duty" cases be defined or identified? Should past participants be notified of any new NHANES disclosure policies (and if so, how?); and how much effort should be made to disclose results?

Key issues of the May 2011 NHANES Genetics Program Workshop were delineated, to include the notion that results should be reported back along with standards, guidelines or best practices (four examples within genetic research with high thresholds for reporting back were noted). Also noted were criteria for clinically relevant genetic findings with a dire duty to warn threshold; who determines this and how and when to report back. Working definitions of clinical relevance, clinical utility and dire duty to warn were presented as was the concept of 'binning by loci' or categorizing potential genetic results. While clinically inconsequential information does not mandate reporting back to research participants, certain information is tangibly useful to subjects. Reporting those with established evidence of health benefits can be accomplished with a locus-based approach to categorization of potential results. Binning the genome was described as was the Evaluation of Genomic Applications in Practice and Prevention (EGAPP). The proposed composition of an advisory board to make the call on dire duty to warn would likely consist of genetic clinicians and epidemiologists, research scientists and bioethicists. Other workshop discussions included how and when to disclose this information relative to one-time re-contracts to inform subjects about consent changes, opt-out for future re-contact and opt-in options. Such an approach would allow for research on clinically relevant conditions although updates would be needed every few years.

Discussion Report of findings issues relative to candidate genes and Genome Wide Association Study (GWAS) analysis were discussed. The meaning and complexities of determining clinical relevance along with implications for researchers and subjects were further explored. Consistent criteria are needed. Ambiguity about whether notifying people helps or hurts was raised. According to the NIH Department of Clinical Bioethics and the IRB, monitoring all medical literature for clinical relevance over time is too high a standard and burden on NHANES. NIH could develop a literature review routine that applies to genomes that have been gathered. The daunting challenge (in time and money) of keeping track of tens of thousands of subjects was raised, noting that respondents can contact the researchers at any time. Another consideration is whether the individual wants to know. At present, new information from genetic testing is coming so fast that to connect with samples from twenty years ago seems unrealistic. It was suggested that subjects be told to contact the researchers after a certain period of time to learn about newly discovered clinical relevance. The NIH

Department of Bioethics has said that blanket nondisclosure rules are not the standard of ethics today.

Dr. Madans raised pros and cons of a proposal to bin or report back to the whole cadre of 30,000 subjects about consent changes with regard to dire duty to warn of genetic results. Experts could examine the criteria to determine what bin things should be reported back. The suggested approach would be difficult without advice from a FACA committee. What are the implications of a program that removes the requirement to not report? What of situations that are still clinically relevant after twenty years? Should the program go back in time or just move forward? Consents have changed. These are some of the questions that NCHS would like input on from the BSC.

Because dire duty to inform may have broad implications across HHS, an advisory group with members from different government agencies (e.g., from OMB; NIH; SAMHSA) was suggested with the BSC as back-up. It was noted that the primary purpose of HANES is to gather descriptive information and repeated cross-sections on major risk factor outcomes. A request was made for NCHS to return to the BSC with a draft proposal of what they would like to BSC to do, relative to these issues. The opening question could be whether to go backwards or forward on reporting and consent structures. It was suggested that the BSC would be a good sounding board because members are not genetics experts although a subgroup to study the issues and make recommendations was again recommended. Another idea was to separate the scientific issues from those impacting NHANES. A description of how the BSC works on division reviews was presented.

Program for Early Release of Selected Estimates from the NHIS

Jeannine S. Schiller, M.P.H. Division of Health Interview Statistics

The evolution of the National Health Interview Survey (NHIS) Early Release (ER) program was presented. In production since 2001, the main report is an internet-only quarterly release about key health indicators (currently 15). Estimates based on early release data versus those based on final data differ by fewer than .03 percentage points. Objectives of the NHIS ER program were presented. Health insurance and wireless substitution have become spin-off reports. New products were described. The main report was more fully delineated to include: indicator selection; a list of current indicators; an indicator example; trend charts; modifications to the ER; future directions of NHIS; changes to NHIS questionnaires with accompanying examples; changes to health objectives; changes requested by subject matter experts; and adding or deleting indicators. The ER is basic and descriptive rather than capable of complex evaluation. Relevant links can be found at the end of the PowerPoint presentation.

Discussion With regard to tracking, web hits and data requests are examined in databases. It is important to track whether important indicators, based on key public health issues, stay put or move forward or backwards. The wireless substitution report is useful as a quality tool. In response to whether flat indicators should remain on the list, one participant thought it would be useful to have them quantified as important supporting evidence. Dr. Sondik asked the BSC to give an opinion on whether the 15 indicators are “good” along with what might be missing from the list. Due to staffing limitations, new indicators would likely replace ones currently on the list. The question of whether learning from this process could be applied to the early mortality reports was raised (noting that mortality has learned to “start small because of indicator creep”). Dr. Hogue announced a resource to the BSC, one part of the PBS series *Unnatural Causes* entitled, “When the Bough Breaks” about black preterm birth, now available free of charge on-line.

Friday, September 23, 2011

Monitoring Health Reform Part I
Addressing the Affordable Care Act and Other Exciting Health Policy Issues

Clarice Brown, M.S. Division of Health Care Statistics

Ms. Brown summarized how the National Health Care Surveys address the Affordable Health Care Act and other changes in healthcare surveys. Issues addressed by health reform were outlined to include: improved access to health care; improved quality of care and evidence-based practice; and a reduced rise in healthcare expenditures. Specific data being gathered and released were presented. Two improvements funded with prevention and public health funds within the Division include an increase in the NAMCS sample size for state-specific estimates and a look-back module that collects data on the care of specific patients with risk factors for heart disease and stroke. The objective is to better assess physicians' clinical management to prevent heart disease and stroke. In addition, ASPR has asked the Division to help monitor the role of emergency departments and health reform. These data will support monitoring the effects of expanding Medicaid program on emergency departments. As such, a new National Hospital Care Survey and the new National Survey of Long-term Care Providers will be launched (report expected end of 2013). Capacity questions have been added to physician-level questionnaires. These projects are "win-win" for NCHS in that they add capacity; allow for computerization of data collection (which improves timeliness); and increases precision of estimates in other areas such as rare diseases and smaller minority groups. Retrospective longitudinal data have also increased. In 2013, the NHAC will be integrated into the Hospital Care Survey. SAMHSA has asked that the Drug Abuse Warning Network (DAWN) be incorporated into the ER sample in 2013 to track substance abuse and mental health issues. This is expected to increase data value, precision and timeliness and allow for linkage.

Discussion Almost 10% of U.S. hospitals are in a linked database. Follow-up questions to physicians are likely to ask whether health information technology will save money. Questions and discussion about the surveys in relation to DAWN and suicide prevention were posed. It is not known whether NCHS is planning compatibility studies for medical records and ER records as ICD9CM moves to ICD10CM. With regard to reproductive and perinatal health, discussion ensued about gathering information about maternal mortality relative to the link between PII in the National Death Index and the Hospital Care Survey. No additional funds are needed to examine Medicaid family planning waiver states in order to compare contraception prescriptions by state (except to increase within-state samples). However, there may not be enough samples to do reliable estimates (although the information might be available through Medicaid MACS data). There is enough sample stratification for rural hospitals but not within state. Although infrastructure improvements are permanent, many of the aforementioned enhancements are funded for 2012 but not beyond. The importance of gathering physician, hospital, emergency room and out-patient data (including admissions to different hospitals) now for future use was stressed.

Monitoring Health Reform Part II
Addressing Provisions of the Affordable Care Act on the NHIS

Robin Cohen, Ph.D. Division of Health Interview Statistics

Enacted in March 2010, provisions of the Affordable Care Act will occur in stages.

Activities from 2010-2011 and beyond were specifically outlined. Questions added to the 2011 and 2012 NHIS were presented relative to access to care; and affordability and comprehensiveness of care along with other related topics such as long-term care and health information technology use. Early release program data about the uninsured (from the first quarter of 2011) were recognized in the New York Times and by President Obama.

Discussion A draft of the 2011 Survey is on the NHIS website but there is no way to identify new questions. However, new questions submitted to OMB can be found at reginfo.gov. It would be useful to establish a structure that enables users to find changes quickly.

Monitoring Health Reform Part III
NHIS 2011 Sample Augmentation

Christopher Moriarity, Ph.D. Division of Health Interview Statistics

The presentation focused on what has been done to increase the NHIS sample size. Augmentation for this year's NHIS was targeted to specific states, using two sources. The specifics of augmentation in U.S. states and Washington D.C. were outlined. NHIS is a personal interview survey within defined geographic areas that must fit into the confines of the Census Bureau's data collection. Budget cuts from previous years have cut the sample, yielding "unused samples" (specifics cited).

Discussion **(questions directed toward all three panelists*)*** The five states added to the sample size are AL, CO, LA, MN and SC, although there may be more. Data provides verification rather than projections. State estimates not previously published will be published although for confidentiality reasons, users will not be able to identify states in public use files. However, researchers with an interest in NHIS data can submit proposals to the Research Data Center. If funding is available, there are plans to significantly augment the sample in 2012 and 2013. How much can be done is also measure-dependent.

Report on Research Data Center (RDC)

Peter Meyer, M.P.H. Research Data Center

All of RDC's data systems produce restricted data. RDC was developed in 1998 to make these restricted variables available to the research community via various modes of access (specifics cited). The major way that data is protected is through RDC's proposal process because researchers must apply for the information they seek. A committee examines a wide range of proposals for technical feasibility and disclosure risk rather than for scientific merit. With back-and-forth communication, the proposal may become a contract. The number of remote users has increased as have Census projects. The average fee for running a NCHS RDC project through to publication is approximately $3,500 while Census RDCs are significantly more expensive.

At present, linkage products and state estimates must come through the RDC. Data hosting is growing (examples given). In addition, there is NHANES with its genetic component and a recent agreement with AHRQ to allow MEPS to be studied in the Atlanta RDC. The website will be expanded and outreach at conferences and universities will resume. Six hundred colleagues from CDC attended a 2010 research series in Atlanta that highlighted all major NCHS data systems. Improvements are being made to IT proposal tracking, the remote access system and to standard operating procedures.

Discussion Only sometimes can information about specific states be extracted from the RDC data (e.g., with HIS, yes; with NHANES, no). Data owners remain the owners within a RDC hosting scenario. They are committee members along with others, any of whom can nix a proposal (a consensus is needed). When a project is finished, its data disappear. Any data in the RDC have all the legal protection of any NCHS data. Found errors are reported back to the researcher. Remote access is taking off slowly and it is not clear why more people are not adopting its use. Procedures available in remote access are limited to some (e.g., currently, there is no remote access for Stata users although it is in development due to greater demand from economists).

Using the NHIS Frame for Web-Based Surveys

Marcie Cynamon, M.A. Division of Health Interview Statistics

The Division has worked with DHHS for the past few years to develop a detailed module on the HIS related to health care reform. The intent is to get consistent measures over time as well as quick measures. The immediate goal was to add questions to the NHIS that would allow for reconnection to people using the web. NHIS's huge sample size and excellent response rates are a "leg-up" for non-response analysis. With such diverse content, targeting can be done multiple times for future follow-ups. Computer use by sample adults has been added.

The enormous challenges in developing this kind of survey were enumerated. Is the HIS appropriate as a launching pad for quick turnaround surveys or as a longitudinal health interview survey? The Whitehouse is thinking about how to use the HIS and web follow-ups to move preventive care forward. What is learned about people eligible for follow-back from their NHIS responses? Health information technology use was examined from various perspectives and timeframes.

Discussion A suggestion was made to ask ASPE or NIH to provide seed money for trial runs. Issues of confidentiality have not yet been addressed although it is seen as a "solvable problem." Addressing confidentiality issues was seen as critical by several BSC members. Survey Monkey is not being considered for web-based surveys at present although the hope is to launch such surveys from HIS sampling frames. Questions to consider include: what do you want to learn from these surveys; what is the impact of certain approaches (via a pilot); and how to recruit. There was encouragement to project planning well into the future (beyond five years). The Biennial Methods Conference is a good forum to examine the state of survey research.

Because web-based surveys have enormous potential, should it lead to another BSC subgroup with additional experts in the field? Its purpose would to further understand the feasibility of doing a web survey. Some felt that BSC was not in the best position to take this on and a decision was made to hold off on creating such a subgroup.

DHHS Plan for LGBT Data and Adding Sexual Identity Questions to the NHIS

Virginia Cain, Ph.D. Office of the Center Director

Identifying issues that measure sexual identity has been a trans-agency effort intended to further the understanding of sexual minority groups, especially relative to health disparities. A range of challenges to measuring sexual identity were presented, to include: conceptual complexity; fluidity of identity; comprehension of terms; commonality of terms; population subgroup differences; and survey design. Results to date include some analysis with NHANES, NSFG and QDRL data (including rates of missing data). The QDRL is developing questions for

the 2013 HIS (process and associated costs described) and on ACASI procedures to make the ACASI process as easy as possible. ACASI and CAPI were defined. The Department is working to assume leadership in obtaining transgender data, using researcher listening sessions to determine health data questions for this complex population. Would respondent-driven sampling be a better solution?

Discussion Only about 20% of the transgender population has surgery so that cannot be used to adequately address identity questions. While several mental health questions exist, a suggestion was made to also incorporate a bullying question. Hormonal changes are health concerns for this population. Access to the transgender population may not be through traditional means.

Public Comment None.

The meeting was adjourned at 11:55 a.m.

To the best of my knowledge, the foregoing summary of minutes is accurate and complete.

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Llewellyn Cornelius, Ph.D., Chair DATE