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# COSSA Washington Update

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Volume 26, Issue 7

April 16, 2007

## NEW NSF EDUCATION HEAD ADDRESSES RESEARCH NEEDS

Cora Marrett, the National Science Foundation's (NSF) new Assistant Director for its Education and Human Resources Directorate (EHR), discussed her ideas about where education research fits into what she called a "scientifically propitious time" for Science, Technology, Engineering and Mathematics (STEM) education. Speaking to the American Research Education Association meeting in Chicago on April 11, Marrett noted that despite much talk and activity regarding STEM efforts, little attention has been paid to the need for "contemporary research" on these issues.

NSF's role is to act as "partnership enablers," Marrett remarked, working with the research community to support efforts to enrich evidence-based education. The key principles of the National Academies' report *Scientific Research in Education* should remain the basis for that enrichment. The principles are: 1) pose significant questions that can be investigated empirically; 2) link relevant research to theory; 3) use methods that permit direct investigation of the question; 4) provide a coherent and explicit chain of reasoning; 5) replicate and generalize across studies; and 6) disclose research to encourage professional scrutiny and critique. According to Marrett, the design of the study should ensure that the research is theoretical, empirical, and replicative. However, a one-size fits all model, such as randomized control experiments given preference in evaluations of No Child Left Behind, is not the answer to investigating all aspects of education, she asserted. What is important is the "rigor" of the design.

Reviewing the current policy context for STEM education, Marrett noted the legislation in the current Congress based on the *Rising Above the Gathering Storm* report, such as the "10,000 Teachers, 10 Million Minds" bill introduced by

House Science Committee Chairman Rep. Bart Gordon (D-TN) and recently enacted by the House, and the “America Competes” legislation introduced in the Senate by its leaders, Sen. Harry Reid (D-NV) and Sen. Mitch McConnell (R-KY). She explained how the report and the legislation use the results of previous education research, yet provides no instruments for further research. In addition, she mentioned how the results of economic research demonstrating the importance of technology to economic growth are often cited, without any discussion of the need to continue these studies by supporting other sciences besides the physical sciences and engineering.

Marrett indicated that the Academic Competitiveness Council (ACC), authorized in the Deficit Reduction Act of 2005 to review the effectiveness of the Federal government’s Math and Science Education programs, will soon issue its report. The ACC has identified over 100 such programs and is charged with recommending ways to efficiently integrate, coordinate, and avoid unnecessary duplication.

She declared that new tools and a supportive environment make the time ripe for improving STEM research opportunities. NSF’s cyberinfrastructure activity allows scholars to operate in virtual communities to conduct complex analyses of key problems. The social and behavioral sciences continue to conduct basic research on learning, child development, and the importance of socio-economic factors on educational achievement, she noted. Finally, Marrett cited recent testimony by Catherine Hunt, the President of the American Chemical Society, to the House Science Committee endorsing the expansion of education research efforts as another indicator that people seek scientific evidence for further commitments to dealing with the many problems facing our education system, not just in the STEM area, but across the board.

## ADVISORY GROUP ON GENETICS, HEALTH AND SOCIETY ISSUES REPORT; EXPANDS ITS CONSIDERATION

On March 26 and 27 the Secretary’s Advisory Committee on Genetics, Health, and Society (SACGHS) held an agenda-packed meeting, including discussions on the Secretary’s Personalized Health Care Initiative, activities of the Office of the National Coordinator for Health Information Technology and the American Health Information Community, status of the Genetic Information Nondiscrimination Act, genetic testing (oversight, role of States and the private sector), gene patents and licensing practices (intellectual property, intellectual property licenses and transfer agreements, private sector role, patents related to genetic testing, and an update on the status of the SACGHS study), the economic consequences of genomic innovation and the evaluation of real-world outcomes of gene-based applications.

The Committee also released its report, *Policy Issues Associated with Undertaking a New Large U.S. Population Cohort Study of Genes, Environment, and Disease* (see related story). According to Reed Tuckson, Executive Vice President of UnitedHealth Group in Minnesota and Chair of SACGHS, “the report describes the foundational questions that must be addressed to help policymakers determine whether the U.S. Government should consider undertaking a new large population study to elucidate the influence of genetic variation and environmental factors on common, complex diseases.”

Chartered in 2002 by the Secretary of Health and Human Services, SACGHS serves as a public forum for deliberation on the broad range of human health and societal issues raised by the development and use of genetic tests and, as warranted, to provide advice on these issues. The Committee is made up of 17 individuals with expertise in disciplines relevant to genetics and genetic technologies. The disciplines include biomedical sciences, human genetics, behavioral sciences, social sciences, health care delivery, evidence-based practice, public health, health services research, health policy, health disparities, ethics, economics, law, health care financing, consumer issues and other relevant fields.

### SACGHS’s Priorities

Tuckson reviewed the Committee’s strategic plan created in 2004 and identified 12 priority issues and study topics. These include the crosscutting issues of: access, public awareness and genetic exceptionalism, which affect all of the Committee’s priorities and “are always addressed.” The Committee has also considered six of its priorities and has produced reports and/or recommendations addressing them. These include:

Vision Statement - The vision statement is designed to serve as a framework for future recommendations. It describes how a future with fully integrated genetics should and should not look and would highlight activities that should be encouraged, identify gaps, barriers, and potential hazards that need addressing.

Genetic Discrimination - The enactment of legislation outlawing discrimination based on genetic information is the Committee's highest priority. Over the past four years the Committee has sent a number of letters to the HHS Secretary championing such legislation, including providing a legal analysis of current law, a compendium of public comments and a DVD documenting the public's "very real concerns and fears."

Education and Training - In 2004, the Committee made recommendations to the Secretary about education and training of health professionals and how it should be enhanced. Understanding that this is largely a public responsibility and acknowledging that the government has a role to play, the Committee asked the questions: Where does education and genetics training stand today? Are we in better shape today than three years ago? Tuckson also noted that the Centers for Disease Control and Prevention (CDC) is planning a major initiative, "Genetics for Early Disease Detection and Intervention (GEDI)," designed to educate the public about genetic-based disorders whose early detection can lead to interventions that can improve outcomes.

Coverage and Reimbursement - In 2006 the SACGHS transmitted a report and recommendations to the Secretary on coverage and reimbursement for genetic tests and services. The Committee highlighted the problems in the system they thought affected patient access and identified nine steps that could be taken to overcome the barriers. The recommendations cover a range of topics, including evidence-based decision making, Medicare care coverage of preventive services, and genetics education for health care providers.

Direct to Consumer Marketing - The Committee sent letters to the Secretary on direct to consumer marketing. This led to enhanced collaborations between the Food and Drug Administration (FDA), CDC, Center for Medicare and Medicaid Services (CMS), NIH, and the Federal Trade Commission.

Large Population Studies - The Committee issued its report (see related story).

The remaining priorities include pharmacogenomics, gene patenting and licensing, and federal oversight of genetic testing. SACHGS released a draft report on pharmacogenomics that is open for [public comments](#) through June 1, 2007 (see below). Gene patenting and licensing is a topic currently under discussion by the Committee. Robert Cook-Deegan, Duke University, Center for Genome Ethics, Law, and Policy in the Institute for Genome Sciences and Policy, updated the Committee on the patent issues related to genetic testing. The Committee plans to pursue further fact-finding surrounding federal oversight over genetic testing. The Committee feels that the issue is relevant to integration of genetic technologies into health care and public health, one of the seven functional areas of its charter. Tuckson noted the extensive consideration given to this issue at its November 2006 meeting, adding that that Centers for Medicare and Medicaid Services will not be moving forward with rulemaking given the "inadequacy of federal oversight framework for genetic tests."

### **Economic Consequences of Genomic Innovations and Real World Applications**

SACHGS is planning to add two new topics for its consideration: the economic consequences of genomics and an evaluation of real world outcomes. The group also began discussing developing a new long-range plan. Tuckson emphasized to the group that he wanted to make sure that there was not "a sin of omission or commission" in the agenda. He stressed that members should indicate anything else they felt was emerging to which the Committee should attend. The Committee's agenda should be "maximally relevant to the events of our time," declared Tuckson.

Noting that one of the "major problems we face in the country today is the extraordinary rapid rise in the overall cost of health care, Steven Teutsch of Merck & Co. Inc., stressed that it "seems like the economic consequences" are something SACHGS should be looking at. One reason to bring it up, he explained is that these consequences of genomics in particular haven't been put in the broadest context. He noted that many of the new technological innovations provide great value, but "there are few that save money in the aggregate."

Teutsch acknowledged that this type of research is going way beyond the mandate of the Committee. There is, however, he noted, no other group doing it. He proposed the group explore the issues they think should be addressed. He identified several issues that occurred to him, including: 1) Who will, should pay for innovation, the

downstream costs? 2) How are we going to afford that? 3) Who is going to benefit - industry, employers, academia, and health care payers? 4) How can the costs be managed to optimize the use of available resources and allocate them wisely? 5) How will these technologies be paid for once developed? What are the rules of the road particularly for insurers, if one is investing in development of technologies, what is the assurance they will actually get coverage? He suggested that a subset of SACHGS bring back an issue brief at the Committee's meeting in July.

Gurvaneet Randhawa, (ex-officio, Agency for Healthcare Research and Quality), cautioned that there are a number of things that need to happen before we can start thinking about using genomics in routine clinical practice, what he calls outcomes research. There are a "huge number of study designs" from randomized clinical control trials to global case control studies. This group of study designs can come from different databases, including health plan databases, Medicare and Medicaid claims databases, electronic health records, and we can launch new prospective studies, Randhawa explained. According to Randhawa, there are three different mechanisms that AHRQ can use to fund these types of outcomes research: 1) the traditional grant mechanism closely modeled on the NIH grant, 2) a cooperative agreement program in collaboration with the FDA called the Centers for Education Research Therapeutics (CERT), and 3) the newly created contract-based program called the DECIDE network designed to look at comparative effectiveness of drugs and devices in diagnostics tests. The next step is to synthesize the data through evidence-based practice centers. The challenge we have is not how we handle the evidence, a daunting task, but how to get the evidence in the first place. That is where the outcomes research comes in, said Randhawa.

He explained that evidence reports are closely paired to decision making. Accordingly, there are a "whole slew of questions that need to be addressed:" what are the benefits, the harms, the net benefit, the added value, the costs, the cost effectiveness, he asked. The next set of challenges is how to implement these decisions. There are the issues of access to care along with changing behavior from early adopters to late adopters. Then you move into the phase of routine clinical use. Other steps could include a feedback loop from the routine clinical use to see, as part of post marketing surveillance if we are achieving the intended benefit or not. Then there are the public health dimensions, he noted.

If the Committee chooses to have a workgroup on the issue, it could provide AHRQ guidance on the gaps in evidence that can be used to make decisions. What are the mechanisms of creating new evidence needed to make decisions? If the existing mechanisms are good enough, how can we better link them? How would we adopt electronic health records? There are both advantages and limitations to using them, he noted. According to Randhawa, it would be useful for SACGHS to think of this as a cross-cutting issue starting with genomics and that can be adopted in other non-genomics processes to identify the outcomes.

Muin J. Khoury, (ex-officio, CDC), noted that there are millions of dollars being spent on genomics to find therapeutics but there is very little being spent outside of that area. When you put it in focus, the role of the Public Health Sciences, genetic health epidemiologists, along with large cohort studies are where the action starts to accelerate the gene discovery. We have made a lot of progress in highlighting what we know and what we do not know about gene disease relationships from a public health perspective, Khoury asserted. He used newborn screening as an example of the confusion that can happen when it comes to policies around genetic information, maintaining that Public Health will have to play a role when we move down the "translation highway," referencing the NIH Roadmap for Medical Research Funding. Khoury added that when things become routine, the questions asked are what is the impact? Who is using it? Do we have disparities? Is it costing more? Have peoples' health outcomes been affected by all of this?

Sadly, said Khoury, the bulk of the investment is in big science, big studies, and big therapeutics. Then it becomes atrophied as we move towards real translation. We need to go beyond going from the bench to the bedside (NIH lingo) to practice, he explained. After that there is there is the dissemination research that looks at outcomes and utilization. This is the research that no one really has a handle on right now, Khoury lamented. Concluding, Khoury noted that there is an overarching concern regarding the evidence of genomic applications, the economic implications, and outcomes research, broadly defined, to include the number of parameters that are crucial to measure in order to have a really good translation of this technology into improving the population's health.

The Committee struggled with how it could play a role but not address specific research. Tuckson suggested that maybe SACGHS's role is to make a case for why this is important, why an analysis of dissemination research that looks at outcomes and utilization is important. They can also do needs' assessment. Then they can raise questions that HHS needs to be able to answer. The Committee decided that these issues were indeed within their purview,

with some refinement. Teutsch was selected to chair a subcommittee. Khoury and Randhawa would also serve in an ex-officio capacity on the subcommittee. They will report on their discussions at the next meeting.

### HHS Secretary Announces Personalized Health Care Initiative

Sheila Walcoff, Counselor for Science and Public Health, Office of the Secretary, Health and Human Services, provided the Committee with an update on the Secretary's Personalized Health Care Initiative. Secretary Michael Leavitt has outlined a course of action for achieving gene-based medical care combined with health information technology, which he calls "Personalized Health Care." According to Leavitt, the plan "will combine the basic scientific breakthroughs of the human genome with computer-age ability to exchange and manage data. . . The Human Genome Project was a dramatic success, but it has correctly been called a race to the starting line. The work that remains is sweeping, from the most fundamental science to the details of health care practice," said Leavitt announcing the initiative at the National Press Club the week prior to the SACHGS meeting.

Personalized Health Care is one of the Secretary's ten priorities that he plans to give a significant amount of his attention, said Walcoff. According to Walcoff, Leavitt's vision for personalized health care is one where "health care is tailored to the individual. Prevention is emphasized. Propensities for diseases are identified and addressed through preemptive intervention. Discovery and innovation move drugs to the market and to medical practice faster and at lower cost." His two-year objective is "to establish concepts and priorities that support health care system transformation to achieve long term objectives."

She described the initiative as resembling a pyramid. Knowledge development and health information technology underpin the foundation for the Secretary's initiative, Walcoff explained. Accordingly, the full potential of the initiative cannot be realized unless the electronic systems, clinical databases, and knowledge repositories currently under development are based on a common set of definitions and standards. There is also an increasing need for and value placed on integrated data sets and higher quality information about efficacy and safety outcomes. By using integrated databases, the ability to assimilate and relate experiences enables incredible predictive power for outcomes in disease management, Walcoff noted. Walcoff posited that as technological capabilities develop across the health care system, better information based on individual differences will aid future medical product evaluation and post marketing assessment of safety and efficacy. An expanded set of health and measurement tools will foster research and development for conditions where there are currently few successful health interventions or preventive approaches.

The top of the Secretary's pyramid is translation into clinical practice. With new tools doctors will play new roles. Understanding the unique aspect of each of us as individuals in health care management requires continued advancement in biomedical research, she explained. This is particularly evident in the need for better bridges between research and health care delivery. At this time, we lack the infrastructure and the analytical strategies for data management and knowledge development across biomedical research and health delivery enterprises. Barriers exist to standardized formats that can enable information exchange among willing partners in our health care. They are hoping to create a health care system, she continued. Walcoff described the Secretary's role in the initiative as "two separate parallel tracks:" technology development and the appropriate policies to support that development.

According to Walcoff, the first track is to link clinical and genomic information to support personalized health care. To do so requires establishing an interoperable public/private data partnership of networks to deliver information on individual medical outcomes and linking findings to genetic laboratory test. It would provide a standardized, open electronic system to link genetic test results used in medical practice and individual response to treatments; deliver to researchers' findings on medical outcomes years faster; provide evidence base for developing more individualized and effective treatment; support pioneering health information technology work for linking clinical data; and helps broaden the evidence base underlying quality of care standards. This link would also allow for the establishment of a common pathway for data integration through electronic personal health records, said Walcoff. The Secretary plans to utilize the American Health Information Community (AHIC) Personalized Health Care Working Group to consider policies or facilitating the inclusion of medial genetic test results and family history information in electronic health records.

The second track is to support the appropriate use of genetic information, including: protecting individuals from genetic discrimination, encouraging policies and practices that provide sufficient protection to consumers that genetic test information is used only for their medical benefit, providing oversight of genetic testing to assure analytical and clinical validity (regulation of testing platforms and systems, and proficiency in practices for



performing tests and data interpretation), and standardizing access policies to federally -funded databases of genetic information. Currently, policies for accessing genetic information are inconsistent regarding who has access to specific information and the time frame in which this information will be made public, and the level it will be made public, Walcoff explained. AHIC is a federal advisory body chartered in 2005 to make recommendations to the Secretary on how to accelerate the development and adoption of health information technology

#### AHIC Working Group on PHC

Walcoff informed SAGCHS that AHIC has established a Working Group on Personalized Health Care (see related story). The Group is co-chaired by Douglas Henley, American Association of Family Physicians, and John Glaser, Harvard Partners. It includes representation from across the federal agencies: AHRQ, FDA, Veterans Administration, Department of Defense, National Human Genome Research Institute, and the National Library of Medicine. There are also representatives from the pharmaceutical industry, health plans, laboratories, consumer organizations, along with individuals from the ELSI (ethical, legal, and social implications) communities. The broad charge to the Workgroup is to make recommendations to the AHIC for a process to foster a broad, community-based approach to establish a common pathway based on common data standards that encourages the incorporation of interoperable, clinically useful genetic laboratory test data and analytical tools into electronic health records to support clinical decision making for the health care provider and patient.

Walcoff noted, however, the lack of consensus on policies surrounding genetic testing, and the inclusion of family history information in the electronic health record which “could impede further systematic and useful adoption of technology.” She also noted that the healthcare system’s acceptance and understanding of new medical technology is not keeping up with the rapid pace of research. Accordingly, the Secretary’s office believes that SAGCHS can assist it in developing knowledge to support some of this work. Walcoff outlined a charge for the group to consider, noting that as part of the personalized health care initiative the oversight of genetic testing is a concern for many stakeholders. The Secretary recognizes this concern and “sees the complexity as the use of genetic technology expands and plays a large role in the personalization of health care.” He is committed to supporting advances and appropriate regulation without stifling innovation, she concluded.

## NEW LARGE STUDY OF GENES, ENVIRONMENT AND DISEASE NEEDS ATTENTION TO SCIENTIFIC, SOCIAL, ECONOMIC, AND ETHICAL PERSPECTIVES

*Policy Issues Associated with Undertaking a New large U.S. Population Cohort Study of Genes, Environment, and Disease* ([http://www4.od.nih.gov/oba/sacghs/reports/SACGHS\\_LPS\\_report.pdf](http://www4.od.nih.gov/oba/sacghs/reports/SACGHS_LPS_report.pdf)), released by the Secretary’s Advisory Committee on Genetics, Health and Society (SACGHS), identifies a range of “salient issues that warrant consideration and further analysis. According to the report, these issue fall into five broad areas: (1) research policy, (2) research logistics, (3) regulations and ethics, (4) public health, social and economic implications; and (5) public engagement. “These are steps that we believe should be carried out expeditiously given the study’s potential benefits, the need for broad public support for such a study, and questions about the feasibility of undertaking it from scientific, social, economic, and ethical perspectives,” notes Reed Tuckson, Executive Vice President of UnitedHealth Group in Minnesota and Chair of SACGHS.

The study is the culmination of nearly two years of deliberation by the SACGHS. The Committee was asked by National Institutes of Health (NIH) Director Elias Zerhouni in 2005 to “focus its inquiry on the preliminary questions that need to be addressed before considering whether” such a study should take place. SACHGS was asked “to identify broad policy and process issues but not to provide answers to the questions raised.”

The topics discussed under the Research Policy section include arguments put forward for and against a new large population study (LPS), the possible effects on other areas of science, the capacity of the current U.S. research system to conduct interdisciplinary science, and the need for public and private and other creative partnerships. Access to the study data and materials collected by other researchers and the complexity of intellectual property concerns are other issues considered by SACHGS.

Based on the knowledge gained from its deliberations, SACHGS “believes that a new LPS in the United States could lead to improved diagnostics, treatments, and preventive measures for common diseases such as cardiovascular disease, diabetes, and cancer. Because of the potential knowledge and health benefits to be gained, SACGHS urges

the HHS Secretary to move forward expeditiously to address the policy gaps identified in this report. Until this analytical work is completed, it will be unclear whether such a study has the broad public support necessary for moving forward and whether the study is feasible from scientific, social, economic, and ethical standpoints.

The report is quite concerned with regulations and ethics related to any large study of people and recommends:

1. *The HHS Secretary should convene a working group of representatives from the Office of Human Research Protection, Food and Drug Administration, Office of Civil Rights, and other relevant HHS and non-HHS agencies to address issues and questions raised by the public to provide technical assistance and guidance to research sites on legal requirements regarding the protection of research subjects, health information privacy, and patient safety.*
2. *The HHS Secretary should establish an independent ethics committee to serve in an advisory capacity to the IRBs and the project leadership.*
3. *The project leadership should systematically and regularly seek the input of study subjects regarding their experiences, concerns, and recommendations for enhancing protections to ensure that the appropriate protections are in place and are being consistently implemented.*
4. *The project leadership should develop a policy regarding the use of data and samples to ensure the legal and ethical use of clinical and epidemiological data and specimens. This policy should be made available to study subjects.*

It also has recommendations regarding Public Health, and the Social and Economic Implications related to the study:

1. *The Secretary and the project leadership should systematically and regularly integrate project findings with other emerging data from other types of studies and regularly disseminate the accumulated knowledge base in a manner to benefit the population's health. This information should be tailored to meet the information needs of the public, health care providers, and the public health community to use integrated information for the benefit of the population's health. Project resources should be sufficient for the integration, dissemination, and translation activities necessary to maximize the public health impact.*
2. *The HHS Secretary, in consultation with the project leadership, should establish an independent standing committee for the duration of the project to periodically assess the persistent and emerging social and economic implications of this initiative, with special attention to health disparities. The committee should consist of individuals with expertise in the relevant sciences, medicine, law, ethics, and patient community advocacy. The committee would routinely seek input from the public on the implications of project results and report its findings.*

Finally, the Report discusses the need for public engagement. To illustrate specific approaches, examples of public engagement efforts used by the National Children's Study and the National Human Genome Research Institute public consultation initiative are described. Two recommendations were presented for consideration.

1. *Before embarking on such a large population study and in advance of any funding decision, the HHS Secretary should assess the public's willingness to participate in such an extensive endeavor.*
2. *If a decision is made to proceed with a large population study, it will be important for the HHS Secretary to ensure that public engagement occurs throughout all aspects and stages of the research process, from conceptualization through design, planning, implementation, conduct, and data analysis and reporting. Public engagement also will be important in applying the knowledge gained by the research and in addressing its implications. The HHS Secretary should ensure that sufficient project resources are dedicated to public consultation activities before and throughout the duration of the project.*

## **SACHGS SEEKS PUBLIC COMMENTS ON PHARMACOGENOMICS REPORT**

The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) is seeking public comment on its draft report to the Secretary of Health and Human Services (HHS), *Realizing the Promise of Pharmacogenomics: Opportunities and Challenges*.

Pharmacogenomics has been identified by SACGHS as a high study priority. The draft report describes the opportunities associated with this area. It also identifies the challenges associated with pharmacogenomics product development and integration into clinical and public health practice. Three major areas are considered: 1) research and development; 2) "gatekeepers" (i.e., those who are involved in facilitating the progression of pharmacogenomics), and 3) implementation of pharmacogenomics to improve outcomes in clinical and public health practice. Draft recommendations also are presented in each area.

SACGHS is requesting comments on all aspects of the draft report and recommendations. In particular, the Committee seeks feedback on the following questions:

- Are the discussions of topics and issues accurate and complete?
- Have any significant opportunities, challenges or other issues been missed?
- Does the draft report adequately describe the range of perspectives on the issues?
- Are the draft recommendations specific enough?
- Are there other strategies for addressing the issues?
- Which draft recommendations should be of highest priority for the Federal government to address?
- Appendix A of the report identifies major pharmacogenomics activities in the public and private sector. Are there other relevant initiatives that should be included in the list?

To download a copy of the report, go to: [http://www4.od.nih.gov/oba/SACGHS/SACGHS\\_PGx\\_PCdraft.pdf](http://www4.od.nih.gov/oba/SACGHS/SACGHS_PGx_PCdraft.pdf)  
Comments received by June 1, 2007 will be considered by SACGHS in preparing the final report.

Comments should be addressed to Reed V. Tuckson, MD, SACGHS Chair, and sent to Suzanne Goodwin by email at [goodwins@od.nih.gov](mailto:goodwins@od.nih.gov), fax at 301-496-9839, or mail to: Reed V. Tuckson, MD, Chair, Secretary's Advisory Committee on Genetics, Health, and Society, NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, MD, 20892 (20817 for non-US Postal Service mail)

## SACGHS DISCUSSES PERSONALIZED HEALTH CARE AND CONFIDENTIALITY, PRIVACY, AND SECURITY OF HEALTH INFORMATION TECHNOLOGY

Robert M. Kolodner, the Interim National Coordinator, Office of the National Coordinator for Health Information Technology (ONC), updated the Secretary's Advisory Committee on Genetics, Health, and Society on its activities. He was joined by Jodi Daniel, Director of the Office of Policy and Research, ONC. ONC was created via executive order April 2004 by President Bush to advance the development of a nation-wide interoperable health structure, along with achieving wide-spread adoption.

Kolodner began by acknowledging that there are multiple challenges to the advancement of genomics, including discrimination on the basis of static information. He stressed it is something that we need to protect against. Genetic information is unique to the individual, predictive of future health and immutable once disclosed, said Kolodner. It not only affects the individual but also family members. The challenge is that genetic information supplemented with other types of data by non-covered entities could be relinked.

Health information technology (IT), Kolodner explained, can really add to genomics, helping advance adoption. The issue of trust in privacy and security is fundamental in order for individuals to allow information to be used and captured now and into the future, he explained further. According to Kolodner, among the drivers for health IT adoption is the increasing cost of healthcare. A robust, interoperable health IT environment brings together electronic health records, personal health records, and public health information. But the purpose of the national health IT agenda is "not to achieve technology," Kolodner explained. It is about the outcome, quality improvements, efficiency, and safety of healthcare, enabling consumers to manage their health. "It is a critical component for a transformation of individual and population health, not just incrementally improving health based on what we are doing today, but bringing about a change in how we support the health of individuals and the nation," he added.

ONC's activities support four strategic goals, he explained: 1) informing health care professionals, 2) interconnecting healthcare, 3) personalizing health management, and 4) improving population health. He highlighted the overlap between SACGHS and ONC, noting that SACGHS's focus cut across the multiple goals that ONC is charged with. He



noted ONC's federal advisory committee, the American Health Information Committee (AHIC), chaired by Health and Human Services Secretary Michael Leavitt, serves to provide input with regard to ONC's advance towards digital health records and interoperability. According to Kolodner, this is how ONC ensures that privacy and security of the records and enable the market forces because in the area of health IT the market processes did not work. ONC's role, however, is not to replace the processes, but to set certain boundaries and targets to remove barriers and provide incentives to enable the market forces to work, he stressed.

Noting that ONC's work is done in work groups (consumer empowerment; chronic care; biosurveillance; electronic health records; confidentiality, privacy and security; quality; and personalized medicine/genomics) whose focus is to make recommendations to AHIC regarding technical, policy, and social issues so the AHIC can then make recommendations to the Secretary and HHS. Kolodner wrapped up his portion of the presentation by stressing that health IT is not the endpoint but the means to improve health. It supports the researcher by making available a variety of tools, providing access to a wealth of information that goes beyond what can be achieved with a normal randomized control study where the population is refined in a very tight manner and where most of the individuals actually have multiple diseases. We will be able to draw that information from the databases. It is really beyond healthcare itself, it is transforming health and care, he asserted.

Daniel drilled down on some of the issues related to privacy and security. Trust is the key to health IT, she contended. Technology clearly provides some added risk for health information to be disclosed. There's greater ability to aggregate, along with a greater ability for a large amount of information to be shared. It also provides "really great opportunities" to protect data in a way much more secure than in the paper world, she added.

ONC's goal is about privacy and security. Nation-wide health information technology infrastructure must ensure patients' identity information is secure and protected. It is a key tenet of everything ONC is doing, said Daniels. ONC sees medical technology and health information technology as having to work hand in hand. "These cannot be developed in the abstract. The policies have to be built as the technology is being developed," she argued. The technology will provide insights on how best the policy goals can be achieved relayed Daniel.

There are areas where health IT may pose additional privacy or security issues that may not have been considered by HIPPA, which always comes up when there is a discussion around privacy and security issues, Daniel noted. With health IT there are "opportunities for greater data sharing, and aggregation, [which] raises questions as to do we have the right policies based on these greater abilities to share and aggregate information." She noted further the ability to aggregate a lot of genetic information and have genetic databases by entities that may or may not be covered directly by existing federal or state laws.

According to Daniel, at the federal level one of the biggest sources of policy development is the Confidentiality and Privacy Work Group whose broad charge is to: *Make recommendations to the Community regarding the protection of personal health information in order to secure trust, support appropriate interoperable electronic health information exchange.* The Work Group also has a specific charge to: *Make actionable confidentiality, privacy, and security recommendations to the Community on specific policies that best balance the needs between appropriate information protection and access to support and accelerate the implementation of the consumer empowerment, chronic care, and electronic health record related breakthroughs.*

Closing, Daniel noted that the workgroup is also very interested in personal health record privacy policy. She explained that the consumer can put information in a health record they control, as opposed to the doctor's health record. Many of these personalized health records, she concluded, are not necessarily covered by state or federal laws.

## NATIONAL INSTITUTES OF HEALTH'S BEHAVIORAL AND SOCIAL SCIENCE RESEARCH FUNDING FOR FY 2006 -2008

The chart below displays the budget numbers for behavioral and social science research funding for Fiscal Years 2006 -2008 for each of the institutes and centers of the National Institutes of Health. For FY 2006 and FY 2007 the chart shows the percent of each Institute's budget devoted to behavioral and social science research. As a result of the Congress' increase in the NIH's FY 2006 budget, the ICs' final budget numbers just recently became available.

Institutes and Centers	FY 2006 Actual*	FY 2006 BSSRF Actual*	%age of Total Budget	FY 2007 Joint Resolution*	FY 2007 Estimate BSSRF	%age of Total Budget	FY 2008 President's Budget
NCI	\$4,747.2	\$305.6	6.4	\$4,797.6	\$305.6	6.4	\$4,782.1
NHLBI	2,893.6	137.4	4.7	2,922.9	137.4	4.7	2,925.4
NIDCR	385.6	17.7	4.6	389.7	17.5	4.5	389.7
NIDDK	1,688.5	144.3	8.5	1,705.9	144.3	8.5	1,858.0
NINDS	1,519.9	128.3	8.4	1,535.5	128.1	8.3	1,537.0
NIAID	4,373.2	36.6	0.8	4,417.2	36.6	0.8	4,592.5
NIGMS	1,916.9	20.5	1.1	1,935.8	20.2	1.0	1,941.5
NICHD	1,252.6	418.9	33.4	1,254.7	418.9	33.4	1,264.9
NEI	660.3	52.4	7.9	667.1	52.3	7.8	667.8
NIEHS	634.9	14.7	2.3	642.0	14.8	2.3	637.4
NIA	1,036.6	268.2	25.9	1,047.3	268.3	25.6	1,047.1
NIAMS	503.0	20.4	4.1	508.2	20.4	4.0	508.1
NIDCD	389.7	81.4	20.9	393.7	80.8	20.5	393.7
NIMH	1,390.0	437.5	31.5	1,404.5	436.4	31.1	1,405.4
NIDA	990.4	454.9	45.9	1,000.6	454	45.4	1,000.4
NIAAA	431.7	203.2	47.1	436.3	202.7	46.5	436.5
NINR	136.0	102	75.0	137.4	102	74.2	137.8
NHGRI	481.4	11.6	2.4	486.5	11.6	2.4	484.4
NIBIB	293.9	1.2	0.0	296.9	1.5	0.0	300.5
NCRR	1,088.5	64.9	6.0	1,133.2	62.7	5.5	1,112.5
NCCAM	120.3	26.6	22.1	121.6	26.7	22.0	121.7
NCMHD	193.5	7.3	0.0	199.4	7.3	0.0	194.5
FIC	65.7	11	16.7	66.4	11	16.6	66.6
NLM	311.9	4.9	1.6	320.8	4.5	1.4	312.6
OD	725.0	28.6	3.9	1,096.4***	26.5	2.4	517.1
BF	81.0	---	---	81.1	---	---	136.0
RMAP	---	1.1	---	---	1.1	---	---
<b>Total NIH (Labor/HHS B.A)</b>	<b>\$28,311.3</b>	<b>\$3,001.2</b>	<b>10.6</b>	<b>\$28,998.7</b>	<b>\$2,993.2</b>	<b>10.3</b>	<b>\$28,771.2</b>

FY 2006 Actual includes the 1 percent across-the-board reduction and the NIH transfer of \$247.3 million from the ICs to the OD for the NIH Roadmap, along with a transfer of \$19.5 million to HHS

\*May not add due to rounding and omission of transfers.

\*\*BSSRF -- Behavioral and Social Science Research Funding, National Institutes of Health, Office of Financial Management

\*\*\*Includes the entire amount for the Common Fund/Roadmap

## TWO NEW NIH DIRECTORS APPOINTED

Griffin Rodgers has been appointed the new director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) by National Institutes of Health (NIH) Director Elias Zerhouni. NIDDK is the lead agency of the NIH's Task Force on Obesity. The Institute also supports the landmark Diabetes Prevention Program (DPP) clinical trial which demonstrated that intensified lifestyle or drug interventions in individuals with impaired glucose tolerance (IGT) prevented or delayed the onset of type 2 diabetes. The full potential of the DPP, unfortunately, has yet to be realized. Cost effective strategies for promoting lifestyle modification leading to weight loss in high risk individuals, in real-world settings, are needed. The challenge for the Institute is how to translate the findings from NIDDK-supported clinical trials in clinical research environments to real world environments.

Prior to his appointment Rodgers served as Acting Director of NIDDK and chief of the Institute's Clinical and Molecular Hematology Branch, which he has headed since 1988. Rodgers received his undergraduate, and graduate and medical degrees from Brown University. He performed his residency and chief residency in internal medicine at Barnes Hospital and the Washington University School of Medicine in St. Louis. His fellowship training in hematology/oncology was in a joint program of the NIH with George Washington University and the Washington Veterans Administration Medical Center. He also has a master's degree in business administration, with a focus on the business of medicine, from Johns Hopkins University.

Barbara Alving has been appointed the new director of the National Center for Research Resources (NCRR). As Acting Director of NCRR, she has overseen the launch of the Clinical and Translational Science Awards (CTSA) program. The CTSA program is a new national consortium of academic health centers designed to transform the conduct of clinical and translational research to ensure that biomedical discoveries are rapidly translated into prevention strategies and clinical treatments for rare and common diseases. The NCRR also provides support to investigators throughout the country to conduct research that ranges from basic and clinical projects to community outreach and education. NCRR funding provides training and research opportunities at minority institutions and colleges, as well as in academic centers located in states that are challenged by distance and low or often rural populations.

Alving earned her medical degree from Georgetown University School of Medicine where she also served as an intern in internal medicine. She completed her residency training, followed by a research fellowship in hematology at Johns Hopkins Hospital in Baltimore. She began her research career at the Food and Drug Administration on the NIH campus. She then joined the Walter Reed Army Institute of Research. In 1997, Alving became the Chief of the Section of Hematology and Oncology at the Washington Hospital Center in Washington, D.C. In 1999, she joined the National, Heart Lung, and Blood Institute (NHLBI), serving as Deputy Director and Acting Director while also serving as the Director of the Women's Health Initiative (2002-2006). In 2005, she was tapped by Zerhouni to be the Acting Director of NCRR. A Professor of Medicine at the Uniformed Services University of the Health Sciences in Bethesda, Alving is also a Master in the American College of Physicians.

## CENSUS BUREAU SUBMITS PLANNED SUBJECTS FOR 2010 CENSUS AND ACS

The U.S. Census Bureau recently submitted to Congress the subjects it plans to address in the 2010 Census and the American Community Survey (ACS). Under law, the decennial census subjects must be submitted to Congress three years before Census Day, which is April 1, 2010. Census Bureau Director Louis Kincannon said the subjects represent the necessary balance between the need for data, much of it required by public laws, and the Census Bureau's commitment to eliminate redundant questions and reduce the time it takes to complete the form.

The 2010 Census would be one of the shortest and easiest to complete since the nation's first census in 1790. Its subjects include gender, age, race, ethnicity, relationship to other people in your residence, and whether you own or rent your home. The Bureau estimates that it will take about ten minutes to fill out.

The ACS, a national sample survey, fully implemented in 2005, meets a critical need to have more timely, current and detailed data on which to base important decisions for all levels of government, community organizations and businesses. In addition to the short-form Census questions, the ACS asks about such social characteristics as: marital status, fertility, grandparents as caregivers, ancestry, place of birth, citizenship, year of entry into the U.S., language spoken at home, educational attainment and school enrollment, residence one year ago, Veteran status and period of military service, and disability.

Economic characteristics on the ACS questionnaire include: income, food stamps recipient, labor force status, industry, occupation and class of worker, place of work and journey to work, work status last year, and vehicles available. In addition, the ACS inquires about the physical characteristics of one's residence: year structure built, units in structure, year moved into unit, rooms, bedrooms, kitchen facilities, plumbing facilities, house heating fuel, telephone service available and farm residence. Information about the financial characteristics related to the residence such as: tenure, value, rent, and selected monthly owner costs, are also requested. The ACS will add questions about health insurance coverage, marital history, and Veterans' Affairs service-connected disability rating.

Next year, the Bureau must provide the question contents to the Congress in preparation for the dress rehearsal for the 2010 count.

## UNDERSTANDING AND PROMOTING HEALTH LITERACY: RESEARCH PROPOSALS WANTED

Low health literacy continues to be a widespread problem. More than 90 million adults, according to the Institute of Medicine, are affected. The Department of Education reports that 43 percent of adults demonstrate only the most basic or below-basic levels of prose. Moreover, the Agency for Healthcare Research and Quality (AHRQ) reports that low health literacy is likely to be a major contributor of adverse health outcomes. Research has linked low or limited health literacy with such adverse outcomes as poorer self-management of chronic diseases, less healthy behaviors, higher rates of hospitalizations, and overall poorer health. Health literacy is a complex phenomenon that involves individuals, families, communities and systems. The complex and cumbersome ways health information is often presented also contribute to the problem.

The National Institutes of Health (Office of Behavioral and Social Sciences Research; Cancer; Heart, Lung, and Blood; Aging; Biomedical Imaging and Bioengineering; Child Health and Human Development; Deafness and Other Communication Disorders; Dental and Craniofacial Research, Environmental Health Sciences; Mental Health; Nursing Research; and the Library of Medicine), AHRQ, and the Centers for Disease Control and Prevention (CDC) have joined together to support an initiative on health literacy.

Applicants should address health promotion, injury or disease prevention, treatment or management of injuries, diseases or health conditions, and/or the improvement of health or health care outcomes within specific populations (e.g., children, the elderly, low income or vulnerable or underserved populations).

The research must involve at least one of the following:

- Health literacy, or one of its many components, as a key outcome;
- Health literacy as a key explanatory variable for some other outcome;
- Methodological or technological improvement to strengthen research on health literacy; and/or
- Prevention and/or intervention strategies that focus on health literacy.

General areas include but are not limited to:

- Nature and scope
- Lifespan and cultural differences
- Impacts and consequences of low health literacy
- Education and training
- Health systems interventions
- Methodology and research technology development

For more information see: <http://grants.nih.gov/grants/guide/pa-files/PAR-07-020.html>

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The Consortium of Social Science Associations (COSSA) is an advocacy organization promoting attention to and federal support for the social and behavioral sciences.

UPDATE is published 22 times per year. ISSN 0749-4394. Address all inquiries to COSSA at [newsletters@cossa.org](mailto:newsletters@cossa.org)

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