

Minutes
Health Research Advisory Committee
November 9, 2011
Pennsylvania Department of Health
Health and Welfare Building, Room 812
Harrisburg, Pennsylvania

Committee Members Present:

Eli N. Avila, MD, JD, MPH, FCLM, Secretary of Health, Commonwealth of Pennsylvania
Lewis Kuller, MD, DrPH, Professor of Epidemiology and University Professor of Public Health,
Graduate School of Public Health, University of Pittsburgh
Arthur Levine, MD, Senior Vice Chancellor for Health Sciences and Dean of the School of
Medicine, University of Pittsburgh (via teleconference)
Michael Parmacek, MD, Herbert C. Rorer Professor of Medical Sciences and Director of the
Penn Cardiovascular Institute, University of Pennsylvania School of Medicine (via
teleconference)
Michael Seiden, MD, PhD, President and Chief Executive Officer, Fox Chase Cancer Center (via
teleconference)
Lisa Staiano-Coico, PhD, President, The City College of New York (via teleconference)
University

Department of Health (DOH) Staff:

Anne Baker, Deputy Secretary for Administration
Caryn Carr, MSLS, Med, Policy Specialist, Policy Office
Keith Fickel, Esq, Senior Counsel, Office of Legal Counsel
Diane Kirsch, RHIA, CTR, Program Manager, Health Research Program, Bureau of Health
Statistics and Research
John Koch, Program Analyst, Health Research Program, Bureau of Health Statistics and
Research
Marina Matthew, RHIA, Director, Bureau of Health Statistics and Research
Stephanie Suran, MHA, Program Administrator, Health Research Program, Bureau of Health
Statistics and Research
Allison Taylor, Esq., Chief Legal Counsel
Michael Wolf, Executive Deputy Secretary

Others in Attendance

John Anthony, Project Associate, Pennsylvania State University
Maja Bucan, PhD, Professor of Genetics, The Children's Hospital of Philadelphia
Lee Harrison, MD, Professor of Medicine and Epidemiology, University of Pittsburgh
Ebbing Lautenbach, MD, MPH, MSCE, Associate Professor of Medicine and Epidemiology,
University of Pennsylvania
Suzanne Scherf, PhD, Assistant Professor of Psychology, Pennsylvania State University
Lauren Stanchak, Intern, Pennsylvania Pharmacists Association

Allen Whisler, Intern, Pennsylvania Pharmacists Association

Call to Order

Deputy Secretary Anne Baker called the meeting to order at 9:07 a.m. on Wednesday, November 9, 2011 in Room 812 of the Health and Welfare Building in Harrisburg, Pennsylvania. Ms. Baker welcomed Committee members and others to the meeting and stated that Secretary of Health, Dr. Eli Avila would join the meeting later. She announced that the purpose of the meeting was to hear presentations from the 2008 obesity research grants and to determine the nonformula research priorities for the 2012-2013 state fiscal year.

Minutes of the September 27, 2011 Meeting

When a quorum of members was present, in person or via telephone, Ms. Baker called for a motion to accept the minutes of the Committee meeting held on September 27th. A motion was made by Dr. Kuller and seconded by Dr. Levine to accept the minutes of the meeting held on September 27, 2011. The minutes were approved by all Committee members.

2008 Nonformula Grant Presentations

Researchers from the four 2008 nonformula grants were invited to present information on the progress of their grants to date.

Presentations:

- Dr. Ebbing Lautenbach, MD, University of Pennsylvania (Penn), summarized the status of their project which focuses on identifying the drivers of Methicillin-resistant Staph aureus (MRSA) cross-colonization in households and includes an intervention for decolonization. The randomized clinical trial (RCT) of the decolonization intervention requires that everyone in the household agree to participate in the study and although there was concern that recruitment of multi-person households may prove difficult, that has not been the case. A total of 274 households containing 1,148 individuals have been enrolled to date. One focus of the project is to test the hypothesis that colonization with strep pneumonia is protective against MRSA colonization. If proven that strep pneumonia elicits an antibody response against staph aureus, it raises the potential for vaccine targets. In response to questions Dr. Lautenbach indicate that 55-65% of families approached agree to participate in the study and that once enrolled 80-85% completed the intervention through to the 6-month follow-up.
- Dr. Lee Harrison, University of Pittsburgh, indicated that while strong infection control departments and antibiotic management programs have done much to reduce hospital-acquired infections, there are still serious infections that are not being prevented. The study seeks to develop and implement approaches to control such infections by three organisms – Clostridium difficile (C. diff), MRSA, and Acinetobacter baumannii (A. baumannii). He reviewed each of the primary aims of the project and progress that has been made. In summary, Aim 1 developed an assay for rapid identification of C. diff carriage with 100% sensitivity and 99% specificity; use of the assay will be implemented as part of C. diff infection control measures in January 2012. Aim 2 showed that introduction of community-

acquired MRSA (CA-MRSA) into the hospital setting has not caused more serious disease than seen with hospital-acquired MRSA (HA-MRSA). Efforts to develop an assay for rapid identification were discontinued since the assay did not perform well due to misclassification; therefore, the molecular basis for the misclassification is being examined. In place of the original aim the study is now looking at MRSA bacteremia and seeking to identify the genes responsible for resistance. Aim 3 developed an assay for identification of *A. baumannii*, which works well to define epidemiology, but work continues as only four loci have been identified. Aim 4 involves modeling to extend findings from study patients to determine the true impact of disease, including economic impact.

- Dr. Suzy Scherf, Pennsylvania State University, stated that the study is designed to understand the mechanisms underlying autism spectrum disorders (ASD) with a particular emphasis on disruptions in brain connectivity and the development of interventions to assist individuals with ASD. This study, looking at disruptions in both structural and functions connections within the brain, involves gene expression and brain mapping studies. The primary intervention seeks to improve face and object processing in high function ASD adolescents. To date only a small number of individuals have completed the intervention and post-training follow-up; however, preliminary results have shown change in brain activation of areas related to face processing. In response to Dr. Kuller's question regarding the genetic vs. environmental origin of ASD Dr. Scherf indicated literature now shows that improvements in diagnosis accounts for apparent increased prevalence and genome-wide association studies indicate ASD more inheritable than schizophrenia or bipolar disease; however, there is still more study needed to understand the environmental impact. Dr. Kuller also questioned the basis for the difference in prevalence between boys and girls. Dr. Scherf stated there is much interest in looking at the differences in brain development of adolescents to better understand why boys are more vulnerable to ASD.
- Dr. Maja Bucan, The Children's Hospital of Philadelphia (CHOP), provided an overview of the five scientific projects of the study which integrate genetic studies, phenotypic studies, animal studies and imaging studies to characterize the common and rare variants associated with ASD and individuals carrying those variants. She also provided a summary of the projects minority training program. Dr. Kuller noted the ethnic and racial variation when looking at the genes being studied and questioned the ethnic breakdown in terms of prevalence in Asian countries such as China or Japan. Dr. Bucan stated there is not good epidemiologic data to state with certainty; however, some data indicate low prevalence in some regions of China, while other regions have extremely high prevalence. Data show that autism prevalence is low in the Amish population while bipolar disease has high prevalence in this population.

Discussion of Final Reports of the 2005 Nonformula Obesity Grants

Marina Matthew, Director, Bureau of Health Statistics and Research stated that at the December 8, 2010 the Committee requested that we allot time to discuss the final progress of recently completed nonformula grants. The 2006 nonformula grants ended May 31, 2011; however, the final progress reports are not yet finalized and the grants must still undergo final performance review. Therefore, staff provided the Committee with the Final Progress Reports, Final Performance Review Reports and Grantee Responses to the Final Performance Review for the five 2005 Obesity grants, and distributed a summary of the Obesity grants to the Committee prior

to the meeting. Further, Ms. Matthew indicated that staff reviewed the Obesity grant documents and determined that none of those grants addressed the biologic link between diabetes and obesity as requested at the September 27, 2011 meeting. At this point Ms. Matthew invited Committee members to share their thoughts on the outcomes of the grants and asked if there are lessons that staff should consider when preparing future Requests for Applications (RFA).

Dr. Kuller commented that the projects were not intended to focus on weight loss but rather they were expected to evaluate the effects of weight loss on biologic characteristics. He expressed concern that what is proposed as the priority focus is not always translated in the projects that are funded. He stated that the specificity of the priority is important to ensure the funded projects are not too diffuse and commented that this is evidenced by the morning's presentations which were quite specific and some of the best presentations to date. Ms. Matthew's questioned whether the problem is in how the RFAs were written or the projects themselves. Dr. Seiden commented that he believes there was not a problem with the design of the projects in that all completed the work they set out to do; rather the reality is that obesity remains an important healthcare problem and as of 2011 no grant mechanism in the U.S. has found a successful strategy for the long term control of obesity. Dr. Seiden further noted that the successful leveraging of additional grants by the funded projects must be seen as a success. Dr. Kuller agreed but restated the fact that the original intent was understanding the pathophysiology of obesity but the projects focused on behavioral interventions likely due to how the RFA was written, how the priority was interpreted by the peer review committee and the type of applications submitted in response to the RFA. Dr. Levine agreed with Dr. Kuller's comments and indicated that while the projects did not accomplish as much as originally hoped, the grants have served as a reasonable platforms for further research and funding by other organizations.

At this point the meeting recessed for lunch.

Introduction to the Discussion of the Potential Nonformula Research Priorities for State Fiscal Year 2012-2013

Dr. Avila summarized the actions the Committee has taken so far with respect to establishing the research priorities. On September 27th the Committee heard testimony concerning the research priorities, followed by a workshop featuring diabetes research experts. After the hearing the testimony, the Committee voted that the research priorities for the formula funds for the 2012-13 state fiscal year should remain the same as in prior years. Then, meeting the Committee discussed potential nonformula priorities during which two areas of interest emerged: the biologic link between diabetes and obesity and comparative effectiveness research focused on improving the delivery of healthcare services. Dr. Kuller agreed to draft a white paper on diabetes and obesity and Dr. Parmacek volunteered to draft a white paper on comparative effectiveness research. Staff emailed the white papers to the Committee members on October 20th. Comments on the white papers were received from Drs. Davis and Kuller and those comments were emailed to Committee members prior to this meeting. Additionally, Dr. Avila stated that prior to the meeting staff emailed to the Committee a White Paper on Marcellus Shale research for the Committee's consideration.

Dr. Avila reminded the Committee and members of the public that according to the Tobacco Settlement Act, the Department has the responsibility to establish the research priorities, in conjunction with this Committee and it is the role of this Committee to advise the Department regarding research priorities that will benefit Pennsylvania citizens. Additionally, the statute requires that, in setting research priorities the Department consider critical research needs to address disparities in health status among various Commonwealth populations.

Dr. Avila explained that objective for this remainder of the meeting was to determine the focus of the research priorities and to determine if the two categories of nonformula funding should be combined for 2012-13. He indicated that after the meeting, staff will prepare the draft language for the selected priorities. The draft wording for the selected priorities will be emailed to the Committee. After the priority language is finalized, the research priorities will be posted on the Department's CURE Web site.

Dr. Avila noted that the Department's Legal Office reserves the right to make additional, nonsubstantive changes after the Committee has finalized the language of the research priorities.

Dr. Avila explained he would call upon each member to ensure each member is given an opportunity to comment prior to a vote on the Committee's recommendations.

Discussion of Potential Priority Areas

Comparative Effectiveness Discussion – Dr. Kuller commented that he thought the priority would emphasize one health condition rather than remain broadly defined, for example to focus on the Medicare population and reducing rehospitalization for congestive heart failure, cardiovascular disease or pneumonia. Dr. Levine agreed but suggested the priority allow for the applicants to propose the clinical entity to be addressed. He also suggested that there is need to look at the genetics and genomics of the population under study and recommended these aspects be added to the priority language. Dr. Parmacek agreed with Dr. Levine and indicated that the projects should have hard end points as indicated by Dr. Kuller but felt those should be defined by the applicant. Dr. Seiden stated he also felt the investigators should be able to propose the clinical entity to ensure that the project outputs are meaningful. Dr. Staiano-Coico commented that to get the most benefit, especially in terms of economic benefit to Pennsylvania, it makes sense to focus on the conditions with the highest rehospitalization rates. She also suggested that, if there are investigators who wish to address personalized medicine from a community hospital perspective there is a need to include a resource list of partners who could handle the genomics aspects. Further discussion centered on the need to ensure requirements for objective, quantitative output measures and a focus on health disparities.

Diabetes Discussion – All members were in agreement that the diabetes paper accurately reflected previous discussion and intent for the proposed research priority.

Marcellus Shale Discussion – Dr. Levine agreed with the comments Dr. Kuller emailed prior to the meeting stating the importance of the topic for Pennsylvania and suggesting that the best approach would be to establish a large cohort study in likely high exposed areas with the collection of baseline clinical and biologic data or, as an alternative to investigate sentinel

increases in risk of disease in affected areas. Dr. Levine also noted that this area of research is so important to the Commonwealth and so potentially costly that this competitive grant mechanism is not the best forum for funding such research. Dr. Kuller stated that the Marcellus Shale White Paper was excellent and if it were to be addressed as a single one year use of funding it would be important to ensure a coordinated effort; therefore he recommended a workshop on the issue to inform the committee of the best way to focus the priority. Dr. Seiden also agreed with the importance of the topic but raised two concerns: (1) currently this impacts rural Pennsylvania with modest population numbers spread over large geographic areas which makes casefinding difficult and (2) the risks will arise over 10-20 year periods while this funding is restricted to 4-year grants. He noted that this funding mechanism is neither large enough nor long enough to establish the robust infrastructure needed to address the issue. Dr. Staiano-Coico agreed that this funding mechanism is not appropriate to address this question. Dr. Avila indicated he has been working on applying for federal grants to start research as suggested by the Committee but he requested the topic be brought to the Committee to discuss whether this funding mechanism may be used to initiate studies on this important subject. Other limitations of the legislative requirements were raised including the fact that the Act defines the types of fundable research, which excludes surveillance in the absence of specific research questions, the peer review requirements and the 50% clinical and health services research requirement.

Committee's Recommendation of the 2012-13 Nonformula Research Priorities

Dr. Avila called for a motion from the Committee to recommend the research priorities. Dr. Levine moved that the research priorities for the nonformula research priorities 2012-2013 be the biologic link between diabetes and obesity and health care delivery comparative effectiveness research blindness and visual impairment, with the understanding that the Department will finalize the language and submit it to the Committee for review. The motion was seconded by Dr. Kuller and passed unanimously. Dr. Avila thanked the Committee for their recommendation and stated he would inform the Committee of the decision regarding the 2012-2013 nonformula priorities soon.

Committee's Recommendation on the Nonformula Funding Categories for the 2012-13 State Fiscal Year

Dr. Parmacek moved that nonformula funding categories, (1) clinical and health services research and (2) other research, be combined. Dr. Levine seconded the motion. The vote was unanimous in support of the motion. Accordingly, the nonformula research priority will include the following sentence: "For the purpose of priority setting and funding, the Health Research Advisory Committee recommends combining the two nonformula funding categories of clinical and health services research and other research."

Plans for 2012 Meetings

Dr. Avila stated that staff will survey the Committee for 2012 meeting date availability in March. Dr. Kuller recommended the first meeting include a workshop on the application of new technologies to measure the human health effects of environmental exposures. The Committee also agreed to continue the practice of hearing public testimony at the first 2012 meeting and to hearing presentations from the 2009-10 nonformula grants on cancer vaccines and blindness and visual impairment at the second meeting.

Adjournment

The meeting was adjourned at 2:00 p.m.