

Genomic Medicine Program Advisory Committee Meeting July 18, 2008

Meeting Minutes

The sixth VA Genomic Medicine Program Advisory Committee (GMPAC) meeting was held on July 18, 2008 at the Hamilton Crown Plaza, 1001 14th Street NW, Washington, DC 20006.

The following GMPAC members were in attendance: Wayne Grody, MD, PhD; Alan Guttmacher, MD (for Francis Collins, MD, PhD); Daniel R. Masys, MD (teleconference); Jonathan B. Perlin, MD, PhD, MSHA, FACP; Brion C. Smith, Col. USA (Ret.), DDS; Annette K. Taylor, MS, PhD; Peter G. Traber, MD; Michael S. Watson, PhD, FACMG; Geoffrey S. Ginsburg, MD, PhD; Muin J. Khoury, MD, PhD.

The meeting was opened by Dr. Wayne Grody, Chair of GMPAC, Dr. Joel Kupersmith, Chief Research and Development Officer (CRADO), VA, welcomed the members and thanked them for their valuable service to the VA. The Under Secretary for Health, Michael J. Kussman, MD, MS, MACP, lauded the committee's efforts and contributions to shaping the future of medicine at the VA.

Program updates were provided by Dr. Ronald Przygodzki, Associate Director for Genomic Medicine. He reported on the completion of the survey project on assessing veteran's attitudes about genomic medicine, the recently launched genetics education initiative in collaboration with the National Coalition for Health professional's Education in Genetics (NCHPEG) as well as scientific and infrastructure updates. In addition, there was a series of presentations by invited speakers.

Ellen Peterson from the Office of General Counsel briefed the committee members on the ethical considerations of membership on a federal advisory committee per the Federal Advisory Committee Act (FACA).

Joan Scott, Associate Director of the Genetics and Public Policy Center (GPPC) at Johns Hopkins University reported on the results of the survey project to assess the attitudes of veterans about genomic medicine. The survey was development based on the themes that arose from focus groups conducted earlier by GPPC. Nine hundred and thirty one veterans receiving healthcare through the VA took the survey. The survey contained information about the genomic medicine program and queried the level of support, willingness to participate, benefits and concerns, design aspects, access to the samples and genetic data etc. In addition, questions on demographics, military service, healthcare and use of VA services were also included. Overall, there was overwhelming support from the veterans for the genomic medicine program with 83% saying that the program should be done and 71% willing to participate.

Willingness to participate strongly and positively correlated with satisfaction with VA healthcare and history of “altruistic” behavior. Protection of privacy was important to 93%. There were divergent attitudes about use of genomic information. A detailed report of the survey results will be published in a peer-reviewed journal.

Dr. Wayne Grody, Professor of Pathology and Laboratory Medicine, Pediatrics and Human Genetics at UCLA gave a presentation on the oversight of genetic testing. The report provided an overview of the current controversy on the definition of a “genetic” test and the challenges therein for providing oversight. The College of American Pathologists (CAP) and the Association for Molecular Pathology define a genetic test more narrowly, limiting it to a test for heritable diseases only, whereas the HHS Secretary’s Advisory Committee on Genetic Testing and the CLIA Advisory Committee define it more broadly to include an analysis performed on human DNA, RNA, genes, and/or chromosomes to detect heritable or acquired genotypes, mutations, phenotypes that cause or are likely to cause a specific disease or condition. Dr. Grody also presented the recently published recommendations of the Secretary’s Advisory Committee on Genetics, Health and Society regarding oversight on genetics testing. The presentation was followed by a discussion of the pros and cons of some of the recommendations, particularly expanding FDA oversight to all tests, whether manufactured kits or laboratory-developed and developing a mandatory, publicly accessible registry of genetic tests.

Dr. Michael Watson, Executive Director, American college of Medical Genetics spoke about workforce development that is needed to incorporate medical genetics into a healthcare setting. He alluded to the fact that the rapid pace of discovery in medical genetics necessitates a dynamic approach to training and implementation of new paradigms of care and that the medical genetics workforce situation is critical, particularly genetic counselors. Although there has been a rise in the number of genetic counselors in the recent years, there is approximately 1 genetic counselor for every 123,600 population. Further, there is a need to improve the medical genetics education component in medical school curricula as well as a need for clinical decision support tools for clinicians to utilize genetic information in patient care.

Dr. Muin Khoury, Director, National Office of Public Health Genomics at Centers for Disease Control (CDC), spoke about closing the gap between genome discoveries and population health. His presentation reiterated some of the points made by Dr. Watson in terms of the need for clinical decision support and electronic health record for the application of genomic discoveries into patient care and public health domains.

Dr. Kevin Hughes, MD, Surgical Director, Avon Foundation Comprehensive Breast Evaluation Center and Co-Director, Breast and Ovarian Cancer Genetics and Risk Assessment Program at Massachusetts General Hospital gave a presentation on clinical decision support, interoperability and potential of electronic health records in large scale identification of women at risk of hereditary breast/ovarian cancer.

His presentation included a demonstration of the software he has developed for capturing family history from various platforms and its application in breast cancer risk assessment.

Dr. Seth Eisen, Director of Health Services Research and Development Service (HSR&D), VA Office of Research and Development, provided an update on the health services genomics initiatives. He described the seven pilot projects that were funded as supplements to existing HSR&D Centers of Excellence. These projects ranged from conducting focus groups to determine barriers and challenges to genomic medicine implementation in VHA, to evaluating models of genetic/genomic medicine, Cost-effectiveness and ethics in genomics research and developing a conceptual framework for the evidence base needed to inform VA policy on genomic medicine applications. Dr. Eisen also provided an update on other initiatives including the Center for Scientific Computing (CSC), Center for Health Informatics Research (CHIR), and Provider Education Research Opportunities, which will play critical roles in the genomic medicine program.

The presentations led to discussion by GMPAC on various topics as they applied to the VA genomic medicine program. The importance of developing informatics capabilities to support the genomic medicine program was at the forefront of the discussion. Dr. Kupersmith, CRADO mentioned that a workgroup has been established between VA and other federal agencies, including CDC and HHS to discuss issues relating to the incorporation of family history tools into the MyhealtheVet, an electronic portal that is currently available to veterans to access their personal health records. The committee also discussed the possibility of the VA serving as a partner in the educational enterprise for genomics and was viewed as an ideal setting for launching such an initiative. In closing, Dr. Muralidhar, DFO, mentioned about the plans for a state-of-the-art workshop on breast cancer genetics and queried the committee regarding their interest to attend. The committee expressed enthusiastic support and interest.

No public comments were received at his meeting.

The next GMPAC meeting is being planned for November 2008 to coincide with the workshop of Breast Cancer Genetics.