

**Genomic Medicine Program Advisory Committee Meeting
October 15, 2007**

Meeting Minutes

The fourth VA Genomic Medicine Program Advisory Committee (GMPAC) meeting was held on October 15, 2007 in the Sonny Montgomery Conference Room, VA Headquarters in Washington, DC.

The following GMPAC members were in attendance: Wayne Grody, MD, PhD; Christine Q. Burt; Francis Collins, MD, PhD; David Gorman; Teri Manolio, MD, PhD (in the afternoon for Francis Collins); Daniel R. Masys, MD; 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.

The meeting was opened by Dr. Wayne Grody, Chair of GMPAC. Dr. Joel Kupersmith, CRADO, and Dr. Timothy O'Leary, Director, Biomedical Laboratory R&D Service and Clinical Science R&D Service welcomed the members and thanked them for their valuable service to the VA. The Under Secretary for Health, Michael J. Kussman and Acting Secretary, Gordon H. Mansfield addressed the committee and thanked them for contributions to shaping the future of medicine at the VA.

Program updates were provided by Dr. Ronald Przygodzki, Associate Director for Genomic Medicine, Dr. Bette Crigger, Chair of the Ethics Advisory Working Group (EAWG) and Dr. Henry Lynch, Chair of the Hereditary Non-Polyposis (HNPCC) Advisory Working Group. In addition, there was a series of presentations by invited VA and non-VA speakers.

Dr. Kathy Hudson, Director of the Genetics and Public Policy Center (GPPC) at Johns Hopkins University provided an update on the progress of the focus groups project to assess the attitudes of veterans about genomic medicine. This project is being conducted through an inter-agency agreement with the National Human Genome Research Institute. She indicated that GPPC was currently in the middle of conducting the focus groups and expects to provide a report on the results to the VA in December. Dr. Hudson reported that there is a strong sense of community among veterans and that they do not have expectations for compensation. She added that there is a concern that participation in genomic medicine research could lead to the loss or denial of benefits. She added that veterans indicated that they would like to be contacted for any future research through the Genomic Medicine Program. Dr. Hudson also stated that with regard to access to genetic samples and genetic data, veterans were supportive of providing access to researchers at other federal health agencies and academic institutions, but not the pharmaceutical industry. When the focus groups have been completed, a survey will be designed to quantitatively test the themes that

emerge from the focus groups. The quantitative assessment is expected to be completed by May, 2008.

Dr. Henry Lynch, Chair of the HNPCC Advisory Working Group provided an update from the group's first meeting, which was held on September 27, 2007. Dr. Lynch gave a brief history of Lynch Syndrome and discussed clinical aspects of this disease from his own work over the last 45+ years. He said that molecular diagnostics have changed the landscape of Lynch Syndrome. He stressed the importance of collecting family history information. Dr. Collins suggested the US Surgeon General's tool, for which the individual patient collects his/her own family history. There was some discussion as to whether this tool could be incorporated into the VA's My Health_{Vet} tool. Dr. Kupersmith said that the VA is looking into this idea. Dr. Lynch also talked about the patient screening algorithms developed by the HNPCC Advisory Working Group for the general population and for patients with moderate/high risk. Specific research recommendations from the advisory working group included a comparison of non-5-fluorouracil to 5-fluorouracil regimens, microsatellite instability (MSI) in African-Americans and financial studies comparing population and moderate/high risk screening.

Dr. Bette Crigger, Chair of the Ethics Advisory Working Group (EAWG) gave a progress update. She announced that the next EAWG meeting will be held on October 16, 2007 and that the EAWG will be joined by Dr. Wayne Grody, Chair of the GMPAC. Issues that will be discussed include informed consent issues among veterans and special considerations with respect to genomic medicine research participants with a severe mental illness, which may lead to impaired decision-making capacity.

Dr. William Duncan, Chief Consultant, Medical-Surgical Services, Office of Patient Care Services (PCS), Department of Veterans Affairs presented the Technology Assessment Protocol used by PCS. This Protocol provides evidence-based recommendations to VA Medical Centers for the purpose of making informed, cost-conscious decisions about new healthcare technologies. The Protocol has four components: the Technology Assessment Program, the Clinical Expert Panel, Utilization and Cost Analysis and the Technology Assessment Advisory Group. The entire process takes about twelve weeks. Dr. Collins asked how PCS obtains accurate, sophisticated advice. Dr. Duncan said that PCS utilizes the VA's medical school affiliations to find people who have had clinical experience with that technology.

Dr. Timothy O'Leary, Director, Biomedical Laboratory R&D and Clinical Science R&D Services presented preliminary results from the Field Questionnaire used to assess genomic/genetic activities at local VA medical centers and VISNs. In terms of clinical care, the majority of genetic tests are performed off-site. Follow-up is needed to obtain a clear understanding of the responses received.

Dr. Sumitra Muralidhar, Designated Federal Official (DFO) for the GMPAC gave a presentation on the collaboration between VA Employee Education System (EES) and the National Coalition for Health Professional Education in Genetics (NCHPEG) on web-based education for inherited colorectal cancer for primary care physicians. The program characteristics will include case-based instruction relevant to VA physicians, content about the importance of family history, information about ordering and interpreting genetic tests for colorectal cancer and web-based access to additional resources. Program development will involve VA physicians, NCHPEG and EES staff, genetic counselors and medical geneticists. NCHPEG will donate relevant content from its current programs.

Dr. Pauline Sieverding, Genomics Portfolio Manager, Health Services R&D Service and Dr. Seth Eisen, Director, Health Services R&D (HSR&D) Service presented an update on Health Services Genomics Research. Dr. Sieverding said that HSR&D is developing a healthcare delivery model that will provide the framework for the planning and delivery of genomic medicine services to the VA patient population. A Health Services Genomics planning meeting was held on September 14, 2007. Recommendations from this meeting included the need for baseline information, discussion of short- and long-term research objectives, research design challenges and the need for research and technical expertise. Dr. Eisen presented information about Clinical Informatics Research, which will improve clinical decision-support systems, knowledge management of evidence-based practices and the tools for patient and provider education and facilitate database development required for characterizing phenotypes. A Clinical Informatics Advisory meeting was held on October 12, 2007.

Dr. Grant Huang, Deputy Director, Cooperative Studies Program (CSP), Clinical Science R&D Service presented an overview of the VA Cooperative Studies Program. The mission of CSP is to advance the health and care of veterans through collaborative research studies that produce innovative solutions to national healthcare problems. CSP is closely tied with the VA's academic affiliates. The Program utilizes a two-tiered review process and a Genomic Medicine Review Board is currently being developed.

The GMPAC discussed the importance of developing informatics capabilities to support the genomic medicine program at the VA. Some of the apparent challenges were discussed in detail. The committee also discussed VA potential for launching studies on pharmacogenomics. Finally, a plan for moving forward with the recommendations of the two Advisory Working Groups was discussed. Dr. O'Leary stated that a scientific and clinical distillation of the recommendations of the HNPCC and Endocrine Tumors Advisory Working Groups will be provided to the GMPAC prior to the next meeting. He also solicited suggestions from the GMPAC members for additional topics for working groups, from either a research or a clinical perspective.

No public comments were received at this meeting.

The next GMPAC meeting is being planned for March 2008.