

**Department of Veterans Affairs
Genomic Medicine Program Advisory Committee Meeting
November 2, 2011
Executive Summary**

The 14th meeting of the Department of Veterans Affairs Genomic Medicine Advisory Committee (GMPAC) took place on November 2, 2011 in Washington, DC. Member Dan Masys opened the meeting with a welcome and introductions of the other members and other attendees, in the stead of the chair, Wayne Grody, who arrived after the introductions and chaired the rest of meeting. The GMPAC members in attendance were Paul Billings, Vence Bonham, Julia Bridge, Dan Wattendorf, Cynthia Morton, Jonathan Perlin, and Michael Watson.

Ronald Przygodzki, Acting Director of the Biomedical and Laboratory Research and Development, delivered an update on the VA Genomic Medicine Program, including the Million Veteran Program (MVP) and other research projects. Mike Gaziano, Director of MAVERIC at the Boston VAMC and Co-Principal Investigator of MVP updated the committee on MVP progress, including current accrual, some aggregate demographics of enrollees. Dr. Gaziano reported that 10,000 Veterans had been enrolled by the end of FY11 and that the goal for FY12 was to enroll 100,000 Veterans. The demographics of MVP participants were reported to be representative of the VA population as a whole. The only significant observation was the low numbers of Veterans in the age group of 18-30. The committee congratulated the program for their recruitment efforts and goals and endorsed an investigation into additional methods for recruitment and enrollment, including the potential for web-based outreach, and potentially enrollment modules, increased social networking to reach a younger Veteran demographic. They also suggested that the MVP research team start to plan for utilization of samples and data from the program.

Larry Meyer, Director of the VA Clinical Genomic Medicine Service and ACOS of the Salt Lake City VA, talked to the committee about the patient care genomics in the VA. Progress in this area included hiring more genetic counselors and the development of Memoranda of Understanding with all VISNs to enable remote genetic counseling to VA sites. Additionally, Dr. Meyer reported on a mandate requiring each VAMC to hire a telemedicine coordinator. Dr. Meyer spoke about the eight VAMCs currently receiving remote genetics consults. The committee suggested that VA explore the possibility of setting up a training program for genetic counselors, perhaps emulating the government/academia partnership of NIH and Johns Hopkins.

Several invited speakers discussed their experiences with similar genetic cohort creation. Dan Masys, formerly of Vanderbilt, spoke about the BioVU program, and an associated study that linked information from the electronic health record with genetic data from stored blood samples. Cynthia Morton, of Harvard University, presented an assessment of the Brigham and Women's OurGenesOurHealthOurCommunity program. Dr. Morton reported that the program was exploring mechanisms to return certain data back to individual participants.. Following these presentations, the committee discussed the recurring issue of the return of individual

research results, and its relation to MVP; this discussion continued into the latter part of the meeting, as well.

Wing Wong, of Stanford University, presented to the committee on innovative informatics from his lab. He reported novel methods for determining haplotypes within whole genome sequencing by using single cell mass spectrometer and methods for compressing whole genome sequence data into much smaller data pieces. Dr. Wong suggested that utility of whole genome sequencing informatics hinged on balancing data speeds with smart power utilization. The committee was very impressed with the data compression idea, and there was additional discussion about how much data to keep, for how long and whether a generic reference sequence was useful for comparative analysis.

Throughout the day, the committee tackled several overarching points about the VA Genomic Medicine Program. In the first, Dr. O'Leary clarified that the main role of MVP was as a platform for research. It is a collection protocol to build up a research resource for future genomics studies by the VA, academic affiliates, and other federal institutions. In another point of discussion, the committee broached the topic of the Genetics Information Nondiscrimination Act (GINA) that was passed by Congress and signed by the President in 2008 to protect genetic information from being used to discriminate on persons for reasons of employment or health insurance. It was reported that this Act does not apply to users of the VHA, who are instead protected by other policies that act in a manner similar to GINA. There was discussion of the difficulty in locating and interpreting these policies. One of the members suggested the possibility of recommending that the VA adopt GINA as a matter of convenience and clarity. The committee tabled further discussion of this topic for a future meeting.

The committee also embarked on a discussion about the likelihood of and ethical issues surrounding return of individual research results from genetic sequencing. Currently, the protocol and consent document of the Million Veteran Program do not allow for the release of any individual research results, but committee consensus was that this might change in the future. The committee was informed that MVP will release aggregate data and that other information will be included in a twice-yearly newsletter to participants. Members were concerned that the non-return of results might be construed as potentially withholding valuable information from participants, and suggested that the program be open to evaluating the need and ways to do this in the future. Further discussion elucidated that the release of genomic data to patients is going to depend on clinical validity of whole genome sequences, but the ongoing lack of consensus on the definition of clinical validity within the scientific community is a hindrance. The concurrence was that the field may have to wait until FDA weighs in on the issue, and the timetable will depend on the community becoming comfortable with the type of data generated, and whether the agency decides to focus on certifying machines and technology rather than analysis.

No public comments were made at the meeting.

The committee endorsed the suggestion of constructing an informatics-working group to convene in the spring of 2012. The Minority and Diversity working group will continue to meet, and the next GMPAC meeting will take place in Spring 2012.



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