

Updates in Specialty Care

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The Million Veteran Program and the Genomic Medicine Service

In 2006, then-VA Secretary Dr. James Peake launched the VA genomic medicine initiative to advance the knowledge of how genes affect health and to promote personalized medicine for veterans.¹ A committee of scientists and veterans' advocates was established to advise the department on emerging issues in genomic medicine. The Office of Research and Development (ORD) rapidly integrated genetic and genomic research into its portfolio, and more recently, patient care services (PCS) initiated a clinical genomics program.

The Genomic Medicine Service (GMS) is the new specialty care service that will provide coordinated clinical genetic and genomic services and assure a high quality of care for veterans receiving genetic counseling and testing.

Thus, genomic medicine in the VA has 2 major components: research and patient care. Genetics has had a major research emphasis for some time, and many assume anything dealing with genetics is research. However, the distinctions between research and clinical care are important, and GMS was established principally to provide clinical care. Separately, the Million Veteran Program (MVP) will build a resource to support genetic research.

THE MILLION VETERAN PROGRAM

MVP will enroll 1 million veterans in a study of how genes affect health and disease. This program will combine information from the electronic med-

ical record (EMR) with analysis of DNA collected from consenting veterans.² When completed, MVP will be the largest biobank and associated database in the world. Currently, 40 sites are enrolling, with planned expansion to 50 sites by August 2013. The goal is to enroll 1 million veterans over the next 5 to 7 years. The availability of this material to researchers will allow detailed and powerful analyses of the role of genes in common and rare adult diseases. Combined with the rich VA EMR, MVP will allow for analysis of the interaction of genes with environmental factors, such as medications and military exposures, which are difficult to address in other populations. MVP will be a living cohort, with participants continuing to update their information, both via questionnaires and the EMR.

While the MVP was being established, the opinions of veterans were key in the design of the study at every step.³ MVP is an opt-in study, with full informed consent. The first contact is a letter and short survey with an opportunity to say "No thanks." If the veteran expresses interest, an ap-

pointment is made to obtain a fully informed consent before enrollment and blood collection. Participants also can withdraw anytime. The study team wants to improve the health of veterans while actively protecting veterans' rights and privacy.

Medically important genes can be identified several ways. Rather than use families for linkage or even current genome wide association studies, future research will explore whole genomes. As the cost decreases, a massive amount of new genetic information relevant to veterans' health will become available. The combination of veterans' electronic records, DNA, questionnaires, and follow-up data they provide will accelerate the pace of identification of genes and gene-environment interactions that will be directly relevant to veterans' health.

DIFFERENCE BETWEEN MVP AND GMS

As a research resource, MVP is not positioned to return research results to individual patients. However, many veterans have questions about the genetic etiology and heritability of their

The VHA's Specialty Care Services includes medical services with a wide range of subspecialties; emergent and urgent care and patient support services, such as nutrition; spiritual care and other specific-purpose programs, such as cancer registry and Centers of Excellence for multiple sclerosis, epilepsy, and Parkinson disease. The Office of Specialty Care Services brings you "Updates in Specialty Care," sharing the latest evidence-based approaches, each column featuring a different topic and providing updates on existing programs, and introducing new programs. Special thanks to Margaret (Maggi) Cary, MD, MBA, MPH, director of the VA's Physician Leadership Development Program, who coordinates and edits the column. Please send suggestions for future columns to margaret.cary@va.gov.



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diagnoses and concerns regarding the impact of their diagnoses for their family's health. The MVP and many other VA genetic studies will help guide the use of existing resources and develop new clinically useful genetic tests; but they remain a fundamental research endeavor. Therefore, a vital need exists for a clinical genomic service.

CURRENTLY EXISTING SERVICES

Genetic services are currently available within the VA, and the current policy is to provide whatever genetic tests are clinically necessary and appropriate for the treatment of the vet-

Prevention (EGAPP), sponsored by the CDC's Office of Public Health Genomics (OPHG), have provided the groundwork for the success of this new venture.⁵ Genetic consultations are currently most often focused on familial cancer traits, such as breast and colon cancer, and neurological or cardiovascular diseases. In these cases, early onset of disease and close relatives with the same condition may suggest a familial cause. However, there are more than 1,500 gene tests currently available. With increasing provision of maternal-fetal medicine in the VA and with new discoveries in

memorandum referenced standards that allow a facility to enter into an agreement with another organization and accept the credentialing and privileging of the service facility. A Memorandum of Understanding (MOU) and a Service Agreement with each facility will allow a genetic counselor in Utah to provide genetic counseling services via telehealth to any other VHA site in the country. Organizing the logistics of the collaboration is next.

PATHOLOGY AND LABORATORY MEDICAL SERVICES

Genetic tests can be relatively expensive, so when one is ordered, there is an effort to assure it is necessary and identify alternatives to testing. GMS may become collaborators in this process, as many genetic counselors are employed by laboratories to provide both gate-keeping services as well as education. Currently, many genetic tests from the VA are sent to other labs, often at a significant cost. At a July 2011 laboratory medicine meeting, there was considerable interest in increasing the capability of VA labs to perform genetic tests and for sharing resources by establishing regional VA labs. Such an arrangement could save considerable cost. Additionally, some DoD labs have sharing agreements, and the new DoD Joint Pathology Lab is expanding the genetic tests it offers.

POTENTIAL PROBLEMS/STRATEGIES

Although local telehealth programs exist, GMS is the first *national* service. Although many sites are providers of telehealth care, they were not necessarily set up to receive consultations. Initial logistical challenges are being identified and resolved: access to and development of VA EMR department notes, collaboration regarding ordering, and identifying private locations for patients to access televideo equipment.

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eran. But access to genetic services and the way in which these services are offered varies significantly among VA facilities. There are a few locations where comprehensive genetic consultation services are available, including Greater Los Angeles and Salt Lake City. Additionally, many centers have expert providers in specialty areas or academic affiliates who accept outside referrals. However, genomics is not integrated routinely into clinical practice, and the general health care workforce is not adequately trained to provide comprehensive genetic services.⁴ It is unreasonable to hire expert genetic providers in all locations, so GMS is expanding its services with available telehealth technology.

The goals of GMS are to provide genetic-related care and support primary care teams and specialty care when genetic issues arise. Several previous VA initiatives and national consortia, such as the Evaluation of Genomic Applications in Practice and

pharmacogenomics and genetic susceptibility to infectious diseases, there will undoubtedly be an expanding scope of genetic services.

TELEHEALTH AND EMR INFRASTRUCTURE KEY

The VHA provides clinical services to roughly 6 million veterans annually, and about 40% live in rural America. In the 1990s, the VHA responded to this service delivery challenge by refocusing its emphasis from a hospital-based system to an integrated outpatient and home-based system. GMS, physically located in Utah, is taking advantage of this system to provide consultations regardless of the location, be it rural or urban.

With the telehealth infrastructure in place, nationally consistent service is afforded through a memorandum from the deputy under secretary for health operations and management titled "Credentialing and Privileging of Telemedicine Practitioners in VHA." That

fortable referring or managing genetic conditions. Therefore, we will develop computerized decision support at the point of care and/or electronic reminders for obvious referrals (such as the patient younger than 50 who has colon or breast cancer). Therefore, ongoing point-of-care education and an ability to identify key staff members at each VAMC as point persons for questions will be needed. Information to identify appropriate genetic consultation candidates and collaborative ways to manage care need to be easily available and as intuitive as possible.

SOCIAL ISSUES

Since the establishment of the Ethical, Legal, Social Implications (ELSI) aspect of the original Human Genome Project, individuals have been aware that there are unique nonscientific issues to address in the field of genetics. With the launch of GMS, several concerns will need to be considered for veterans and their families. The role of the genetic etiology in the predisposition to a particular condition may be of concern to some veterans who fear about losing service-related benefits if it is deemed that their condition is genetically rather than environmentally caused. Most adult-onset conditions are inherited in a multifactorial manner, so even with a genetic predisposition, manifestation of symptoms typically requires an environmental insult. Understanding the complexity of gene and environmental interactions is the focus of much research, and much is still unknown. Policies to assure that veterans will not lose benefits as a result of genetic testing will be essential.

Finally, genetics is about families. When Abraham Lincoln in his second inaugural address said, "...to care for him who shall have borne the battle and for his widow, and his orphan..." he was not likely thinking about genetics, but he could have been. Although

often valuable for understanding the etiology of a diagnosis and thereby managing treatment for an individual, genetic testing is also useful for the health of extended family members. Many veterans ask about genetic implications of their diagnosis on behalf of their children, and GMS is prepared to address those emotional concerns with both genetic counseling and family educational materials as appropriate.

CONCLUSION

The VHA has identified a unique opportunity to provide genomic medicine to our veterans. This article outlined the rationale, infrastructure needs, and processes that are involved in the implementation of a comprehensive, coordinated, national genetic counseling and diagnostic evaluation service. Genetic services will be unique to VHA in that the formal service will exist primarily from one location, although local resources will continue to be available. In addition, with the launch of a parallel, large research effort, the MVP supplementing the many individual genetic research projects already ongoing, and the ready availability of researchers to investigate the program as it is launched, this service will be able to take advantage of real-time evaluation. Because genetics is a popular topic in both the scientific and public press, many individuals are aware of it, especially its social implications. Greater awareness allows for powerful discussions about the social issues that need to be resolved. Once established, GMS will have a significant impact on the 6 million veterans—and their families—who seek health care from a VHA facility.

Acknowledgement for the MVP

Credit for The Million Veteran Program: A Partnership With Veterans goes to the Office of Research and Development (ORD) and the project's principal investi-

gators, along with many others, who put years into the organization and implementation of this project. At ORD, Drs. Timothy O'Leary, Sumitra Muralidhar, and Ronald Przygodzki were key in the planning stages with the support of Dr. Joel Kupersmith. The project's principal investigators, Drs. Michael Gaziano and John Concato and the Informatics and Biobanking leads, Drs. Louis Fiore, Leonard D'Avolio, and Mary Brophy, also deserve specific recognition. Finally, credit goes to the dozens of others involved in the planning at multiple levels and to all of the local investigative teams—a true cast of hundreds.

Author disclosures

The authors report no actual or potential conflicts of interest with regard to this article.

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