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Study of Clinical Genome Sequencing in the Active-Duty Military Begins

The MilSeq Project, a research collaboration between the U.S. Air Force and academic sites, explores the use of DNA sequencing in routine care of healthy Air Force service members

Boston, MA— Up to 75 active-duty U.S. Air Force service members will now have the first opportunity to incorporate whole exome sequencing (WES) into their routine clinical care through a new two-year research partnership between the Air Force Personalized Medicine Program, Air Force Medical Genetics Center and several academic institutions, including Brigham and Women's Hospital, Broad Institute, Harvard Medical School and Baylor College of Medicine.

In a presentation today at the 2017 American Society of Human Genetics Annual Meeting in Orlando, Fla., the design and early implementation of this research study were described and special considerations that are unique to genome sequencing in the active-duty military were presented by Megan Maxwell, MS, CGC, a genetic counselor leading the study implementation.

The pilot project has already begun recruiting ostensibly healthy Air Force service members stationed at Lackland Air Force Base (AFB) in San Antonio, Texas. The research team is also recruiting 15 active-duty Air Force Primary Care, Internal Medicine and/or Family Practice healthcare providers who will disclose results to the study participants. Air Force health care

providers will receive an educational primer in genomics and have on-site genetic counseling support. They will receive a customized report that provides pathogenic and likely pathogenic variants for dominant and recessive monogenic conditions, pharmacogenomic variants and risk variants for common complex diseases that will be permanently entered into the service member's medical record. Drawing upon prior research projects in the civilian population, the investigators will track medical, behavioral and economic implications of providing this information to active-duty service members. The study will also track any subsequent medical repercussions among participants' family members that may result from the testing of the service members.

“It is important to understand the unique benefits and challenges of incorporating genomic medicine in a military population,” said Maj. Cubby Gardner, joint principal investigator of the study at Lackland AFB. “We need to explore how sequencing may or may not affect the perception of fitness for duty, how the finding might influence clinical decision making among military clinicians, and how knowledge of the findings might impact the individual's downstream healthcare utilization.”

The integration of genome sequencing in the day-to-day medical care of healthy individuals is widely expected to occur throughout all aspects of society in the coming decade, but is still controversial because risk information generated by genomics is often imprecise and the downstream medical consequences are not well understood.

“We are determined to bring cutting edge clinical care to military personnel and their families,” said Lt. Col. (Dr.) Ruth Brenner, Chief of Personalized Medicine, Air Force Medical Support Agency, who was an early champion of the study. “This observational trial will allow us to test the feasibility and measure preliminary outcomes associated with integrating genomic information into everyday medical care, and downstream, to rigorously evaluate clinical utility and cost.” The study is also co-led by Capt (Dr.) Mauricio De Castro of the Air Force Medical Genetics Center who hopes to accelerate the integration of high quality clinical genome sequencing into the Air Force.

“By launching this study now, before sequencing becomes commonplace, we are hoping to ensure that active-duty military personnel will benefit from accelerating trends in genomic medicine,” said joint principal investigator Robert Green, MD, MPH, director of the Genomes2People Research Program at Brigham and Women’s Hospital and Professor of Medicine (Genetics) at Harvard Medical School. “The special considerations around fitness for duty and privacy make this a particularly challenging study to design and implement, but also an extremely important domain in which to gather empirical data around benefits and risks.”

The MilSeq Project (formally titled “Enabling Personalized Medicine through Exome Sequencing in the U.S. Air Force”) is supported by Air Force Medical Support Agency contract number FA8650-17-2-6704 and is co-led by Major Gardner and Dr. Green. The views expressed here do not reflect the official views or policy of the Department of Defense or its components. The full and voluntary informed consent of the subjects participating in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402.

MilSeq Project Poster Presentation (#581T): Special Considerations for Genomic Sequencing Research in the United States Air Force: Development of the MilSeq Project will be presented on Thursday, October 19 from 2-3pm in the Convention Center Exhibit Hall, Level 1, at the 2017 Annual Meeting of the American Society for Human Genetics.

The Genomes2People Research Program at Brigham and Women’s Hospital, the Broad Institute and Harvard Medical School is directed by Robert C. Green, MD, MPH and conducts empirical research in translational genomics and health outcomes. NIH-funded research within G2P seeks to understand the medical, behavioral and economic impact of using genetic risk information to inform future standards for implementing genomic medicine. The REVEAL Study has conducted several randomized clinical trials examining the impact of disclosing genetic risk for a frightening disease. The Impact of Personal Genomics (PGen) Study examined the impact of direct-to-consumer genetic testing on over 1000 consumers of two different companies. The MedSeq Project has conducted the first randomized clinical trial to measure the impact of whole genome sequencing on the practice of medicine. The BabySeq Project is recruiting families of both healthy and sick newborns into a randomized clinical trial where half will have their baby’s genome sequenced.

Brigham and Women's Hospital (BWH) is a 793-bed nonprofit teaching affiliate of Harvard Medical School and a founding member of Partners HealthCare. BWH has more than 4.2 million annual patient visits and nearly 46,000 inpatient stays, is the largest birthing center in Massachusetts and employs nearly 16,000 people. The Brigham’s medical preeminence dates back to 1832, and today that rich history in clinical care is coupled with its national leadership in patient care, quality improvement and patient safety initiatives, and its dedication to research, innovation, community engagement and educating and training the next generation of health care professionals. Through investigation and discovery conducted at its Brigham Research Institute (BRI), BWH is an international leader in basic, clinical and translational research on human diseases, more than 3,000 researchers, including physician-investigators and renowned biomedical scientists and faculty supported by nearly \$666 million

in funding. For the last 25 years, BWH ranked second in research funding from the National Institutes of Health (NIH) among independent hospitals. BWH is also home to major landmark epidemiologic population studies, including the Nurses' and Physicians' Health Studies and the Women's Health Initiative as well as the TIMI Study Group, one of the premier cardiovascular clinical trials groups. For more information, resources and to follow us on social media, please visit BWH's online newsroom.

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