POLICY IMPLICATIONS OF USING GENOMIC MEDICINE

IN

THE AIR FORCE MEDICAL SERVICE

by

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Biography

Lt Col Kevin Wright is an Air War College student at Maxwell AFB, AL. He formerly was the Pharmacy Flight Commander, 45th Medical Group, Patrick Air Force Base, FL, and the Air Force Space Command Pharmacy Consultant.

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His staff experience includes Program Manager for the DoD’s Joint Deployment Formulary and Program Manager for the $3.2B DoD/Food and Drug Administration Shelf Life Extension Program.

He deployed as the Pharmacy Flight Commander, 332d Expeditionary Medical Group, Balad, Iraq, and again for one year on an Embedded Training Team where he trained the staff of Kandahar Regional Military Hospital and coordinated trauma care for the 27K soldiers of the Afghan National Army 205th Corps’ in Southern Afghanistan.
Introduction

Researchers launching the Human Genome Project (HGP) in 1990 knew the outcome would forever change science and medicine but could not have comprehended all of its second and third order effects. Yet, they had the foresight to invest not just in scientific research but also in the associated ethical and legal issues.\textsuperscript{1,2} For over two decades their work has generated controversy and awe while giving rise to the field of genomic medicine.

Integrating genomic information into medical practice offers unique insights into an individual’s make-up, facilitating advancements in prevention, diagnostics and therapeutics but at the same time raising concerns about discrimination. The issues surrounding genomic medicine are complex and, at times, clouded by emotion. While genomic medicine offers the Air Force Medical Service (AFMS) the promise of improved care it requires foundational policies to protect the patient, the provider and the government from discrimination and discrimination-based lawsuits due to availability and use of patient-specific genomic data. This paper begins by reviewing the history of human genome mapping and its implications for medicine thus far. Next, it reviews the key issues of discrimination, patient privacy, legal protection and genetic exceptionalism. Then, making the assumption that genomic testing will soon become the standard of medical care, it advocates for a comprehensive policy to protect Airmen from discrimination and invasions of their privacy. It also proposes use of accession-level genomic screening to accompany the integration of genomic information into medical practice. Finally, it explores how to mitigate risks associated with the use and storage of

\textsuperscript{1} Joint NIH-DOE Ethical Legal and Social Implications Working Group of the Human Genome Project, Task Force on Genetic Testing, National Human Genome Research Institute, \url{http://www.genome.gov/pfv.cfm} (accessed October 6, 2010).
genomic information and concludes with specific recommendations to AFMS leadership that should precede widespread use of genomic information.

**BACKGROUND**

Laboratories around the world completed the HGP in 2003 using a composite research sample from multiple donors.³ Mapping of the first individual’s DNA occurred in 2005. That DNA belonged to Dr James Watson, Human Genome Project architect and joint discoverer of DNA structure in 1953.

Mapping the human genome sequence was a fantastic achievement providing fundamental data, such as accurate estimates of the number of genes and the billions of base pairs comprising DNA. It also established a starting point for thousands of discoveries to uncover the function of each gene. Genome mapping unlocked both the promise of genomic medicine, including new and exciting medical diagnostic and treatment options, and the threat of genetic discrimination.

Discussing genomic medicine and genetic discrimination can be confusing because of the similarity of the terms genetic and genomic. Medical genetics is defined as the study of single genes and their effects, e.g. Huntington’s Disease.⁴ It encompasses testing of genotype, actual DNA encoding, and phenotype, the physical manifestation of the gene. Medical genomics, a term coined within the last 15 years, is the study of the functions and interactions of all genes in the genome.⁵ The field of genomics is much broader in scope and its medical contribution will be uncovering the mechanisms of common but complex diseases, such as Parkinson’s and

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⁵ Guttmacher, 1512.
Alzheimer’s, which can involve multiple genes and environmental interaction. Unfortunately, most legislation uses the term “genetic” when discussing both genetic and genomic information. This paper uses the above definitions throughout.

The introduction of genomic data into medicine creates new opportunities to improve care.\(^6\) In fact, Dr Francis S. Collins, Director of the National Institutes of Health and Former Director of the National Human Genome Research Institute, states, “the practice of medicine has now entered an era in which the individual patient’s genome will help determine the optimal approach to care, whether it is preventive, diagnostic, or therapeutic.”\(^7\)

Genetic information is widely used in screening and diagnosis. For example, screening can identify risk of breast cancer in carriers of the BRCA gene. On the other hand, genomics offers the promise of integrating complete genome information with family and medical histories to assess disease risk while providing an opportunity for education about inheritance, testing, management, prevention, resources and research.\(^8\) These benefits can be valuable for both patients and their families. For instance, empirical studies show that 60% of women at high risk for breast cancer choose genetic testing to provide information to their children, yielding monitoring and intervention opportunities that improve outcomes.\(^9,10\)

Similarly, the new field of pharmacogenomics has expanded understanding of both pharmacokinetics and pharmacodynamics, improved prescribing decisions and drug dosing, and

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\(^7\) Guttmacher, 1515.

\(^8\) Joint NIH-DOE Ethical Legal and Social Implications Working Group of the Human Genome Project.

\(^9\) Peshkin, 4.

maximized drug effectiveness while minimizing side effects. For instance, new research found 13 single nucleotide polymorphisms (SNPs) which are strongly associated with a loss of function mutation in the CYP2C19*2 allele, the enzyme that activates the drug clopidrogel. This mutation is associated with lower drug activity, a decreased antiplatelet effect and an increase in cardiovascular events in patients taking the drug.\(^{11}\) Knowing a patient has this mutation allows the provider to select a different, more effective drug. Similarly, in 2007 the FDA directed modification of warfarin prescribing information to “highlight potential relevance of genetic information” after discovering patient response can vary 10 fold due to polymorphisms in two genes encoding proteins for warfarin activity.\(^{12}\) One supporting study found nearly half of all new patients would receive inappropriate doses if given the standard warfarin dose.\(^{13}\) Prospective dosing recommendations incorporating patients’ genotype now exist for warfarin, atomoxetine, irinotecan and many antidepressants. These recommendations help providers prospectively adjust doses and minimize adverse drug reactions in patients with variant alleles.\(^{14,15}\)

**KEY ISSUES**

The improvements in care described above are accompanied by several challenges. First,
the required technology is currently prohibitively expensive, which limits widespread acceptance and use. However, Dr Amy McGuire, an ethicist at the Center for Medical Ethics and Health Policy at Baylor College of Medicine, predicts that affordable testing will allow integration into routine clinical care by 2012. Additionally, the medical community as a whole is not prepared to integrate genomic medicine into primary care. Studies indicate that “primary care physicians and other non-genetic specialists have a lack of knowledge, understanding, and interest in medical genetics.” While medical personnel and the public must be educated about this emerging field, clinicians, ethicists, lawyers and policy makers must reach consensus on several key issues before genomic information is widely incorporated into AFMS practice.

**Genetic Discrimination**

The first issue, genetic discrimination, is defined as “the discrimination that results against an individual or a member of an individual’s family solely on the basis of that individual’s genotype.” It is likely to arise “when genetic factors indicate that a currently unaffected individual is at an increased risk of developing a physical or mental impairment at some time in the future.” In this case, assessment of increased future disease risk that was revealed only by genetic factors may be used against the patient.

Fear of genetic discrimination by health insurers and employers is well founded and cases of discrimination exist for each. Prior to signing of the Genetic Information Nondiscrimination Act (GINA) of 2008, insurance companies could charge higher premiums or refuse insurance if their required testing indicated increased risk of genetic disease. This should not have been a

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19 Rothstein, 28.
problem within the Air Force because health insurance is an unqualified benefit to all active-duty members and their legal-dependents following appointment of the sponsor to active status. However, GINA should provide protection to active duty and dependents after leaving military service.

While insurance discrimination should not be an issue for the Air Force, genetic-based employment discrimination has the potential to be. Limited discrimination is authorized in accessions in order to fulfill national security requirements. DoDI 6130.03, Medical Standards for Appointment, Enlistment, or Induction in the Military Services, establishes accession medical screening by defining diseases incompatible with military service but it does not address genetic or genomic testing.\(^{20}\) Interestingly, the Air Force was the defendant in an early case of genetic-based employment discrimination. A 1979 decision to deny admission to the Air Force Academy to persons with sickle-cell trait led to a suit alleging the decision disproportionately impacted blacks.\(^{21}\) Civilian experience shows that risk of employment discrimination increases with increased availability of genetic and genomic information.

In spite of a large body of legislation, active duty members still have minimal protection against genetic-based, employment discrimination. Most states have enacted legislation banning genetic-based employment discrimination. Specifically, 47 protect against health insurance discrimination and 35 offer protection against employment discrimination.\(^{22}\) In addition, Executive Order 13145, signed in 2000 by Pres Clinton, prohibits discrimination in Federal

\(^{22}\) Beth N. Peshkin and Claudine Isaacs, “Genetic Counseling and Psychosocial issues in Women with an Inherited Predisposition to Breast and Ovarian Cancer,” UptoDate, \url{http://www.uptodate.com} (accessed August 26, 2010).
employment based upon genetic information.\textsuperscript{23} Conversely, Department of Defense Instruction 1020.02, Diversity management and Equal Opportunity in the Department of Defense, does not protect active duty members against discrimination based upon genetic information. It only prohibits discrimination based upon race, color, religion, sex or national origin.\textsuperscript{24}

Even the relatively newly enacted GINA is silent with respect to protecting active duty members. This federal legislation “prohibits health insurers and employers from asking or requiring a person to take a genetic test and from using genetic information in setting insurance rates or making employment decisions.”\textsuperscript{25} Although GINA is the primary legislation protecting genetic data, it does so by revising existing legislation that minimally effects DoD, i.e. Americans with Disabilities Act, etc.\textsuperscript{26,27,28,29} Thus, regulations protecting today’s Airmen are yet to be written.

**Privacy Issues and Legal Protection**

Closely related to discrimination is the issue of privacy. Reports of unauthorized access or use and inadvertent release of information are commonplace. Compounding the concern is the indefinite length of time that DNA samples can be held, allowing analysis many years after sample collection and potentially long after the patient forgot the sample even existed. It should come as no surprise then that in a 2004 survey of 4,834 Americans 80% of respondents opposed

\begin{itemize}
\item \textsuperscript{23} Baruch, 437.
\item \textsuperscript{25} Baruch, 435.
\item \textsuperscript{27} U.S. Code, “Title VII of the Civil Rights Act of 1964,” SEC. 2000e-16, Section 717.
\item \textsuperscript{28} U.S. Code, “Title XLII, Employment by Federal Government,” Chapter 21, Subchapter VI, SEC. 2000e-16.
\item \textsuperscript{29} U.S. Code, “Title V, Military Departments,” Part 1, Chapter 1, SEC. 102.
\end{itemize}
health insurer access to genomic data and 92% opposed employer access. Further, over 50% of respondents in a 1998 survey would not take a genetic test if their employer or insurer could obtain results. Clearly, concerns over privacy and discrimination are at the heart of this opposition.

That notwithstanding, patients have privacy rights rooted in law. Constitutional amendments (4, 5 and 14) and tort law lay the legal groundwork and the right to be “let alone” is established by common law. These rights are not without bounds, however. In a relevant statement the Supreme Court ruled “a person has no legitimate expectation of privacy in information he voluntarily turns over to third parties.” This ruling could impact control of health information. Once a person releases information for uses ranging from employment physicals to life insurance, they lose control, and potentially recourse, over where their personal information subsequently goes.

Three legislative approaches exist for addressing privacy and discrimination concerns; privacy-based, antidiscrimination and equality-based. Privacy-based protection operates by sequestering the information and controlling access, (e.g. Privacy Act of 1974). An antidiscrimination approach does not attempt to protect the data but instead prohibits specific actions based on genetic information, (e.g. GINA). Congress has used these two approaches concurrently to not only limit access to patient information but also to protect individuals if it

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33 Krumm, 512.
34 Silvers, 377.
falls into the wrong hands. Finally, the equality-based paradigm operates similar to bans against race and sex discrimination, (e.g. Civil Rights Act). The equality-based paradigm is discussed in greater detail later.

**Genetic Exceptionalism**

“Genetic exceptionalism” argues that a person’s DNA contains the most intimate information about them, their ancestors and descendants; therefore, genetic information warrants special protection. Efforts to create special protection for genetic information began long after providers started using the information. The delay was likely caused by its gradual appearance in medical records in the form of hemophilia, sickle cell or cystic fibrosis tests, not as a full genome. As a result the information was protected like other medical information, which explains its ubiquitous presence throughout the medical record instead of segregation in a separate record. Although concerns over its uniqueness were not voiced until breakthroughs allowed mapping the entire human genome, they are at the core of the genetic exceptionalism argument. While many commentators dispute this concept, legislators use it as the foundation of genetic antidiscrimination laws because it is easier and less contentious to add protection from genetic discrimination using this approach than to rewrite existing laws into the equality-based approach.

Nonetheless, use of the genetic exceptionalism argument demonstrates that it is difficult to define and legislate boundaries around the complex issues of genetic and genomic information. In “Genetic Exceptionalism & Legal Pragmatism” Mark Rothstein, an ethicist with the Institute for Bioethics, Health Policy and Law at the University of Louisville School of

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35 Ojha, 385.
Medicine, states that 3 conditions must be met for genetic-specific laws to be “successful”: (1) the term ‘genetic’ must be defined clearly and precisely; (2) there must be an inexpensive, efficient means of segregating genetic from non-genetic information; (3) and there must be capacity and reason to do so.\(^{37}\) He describes the problem well by stating, “(one) cannot hope to single out for special underwriting or access health information that is ubiquitous and impossible to define, that cannot be feasibly segregated from other health information, and that cannot logically be treated specially.”

On the other hand, the newness of genomic data is likely one of the significant sources of fear and concern over its perceived uniqueness. Rothstein describes this as a self-fulfilling prophesy. “It is unique partly because genetic-specific legislation bolsters that view.”\(^{38}\) Since an individual’s current and future health status can already be predicted using family history and certain socioeconomic variables without need for genomic testing, he argues that genomic information is not unique. For example, sickle cell anemia is a genetically determined disease, but it is not necessary to do genetic testing to identify it or to confer risk to offspring. Conversely, one can argue that a complete genomic profile is quintessentially unique. Like a patient’s fingerprint, it cannot be de-identified because it is unique to that specific patient. One could further argue that concerns over protecting genetic information are misplaced, with the real point being protecting genomic information.

Genetic information has been used in medicine for decades and further restrictions on its use would impede the ability to provide medical care. Even GINA does not require segregation of the information by medical providers.\(^{39}\) Here this author differentiates between use of

\(^{37}\) Rothstein, 28.
\(^{38}\) Rothstein, 30.
\(^{39}\) U.S. Equal Opportunity Commission, Sec. 206.
genomic information and the information itself. A provider’s note referencing a patient’s risk of heart disease or cancer that was discovered from the genome is medical information falling under existing protection. The genome itself, however, warrants additional protection.

**AREAS FOR NEW POLICY**

Prior to integrating genomic medicine into practice the AFMS must establish policy to guide its use. Several specific areas must be addressed, beginning with accession screening.

**Accession-Level Genomic Screening**

Genomic information has the potential to enhance accession-level medical screening. DoDI 6130.03 excludes individuals with “medical conditions or physical defects that may require excessive time lost from duty for necessary treatment or hospitalization, or probably will result in separation from the Service for medical unfitness.”40 (emphasis added) By identifying in advance and not accessing these individuals the Air Force can avoid manpower shortages, wasted training dollars, and even safety issues. More important are the benefits to individuals who avoid exposure to operational environments that could negatively affect their health.

Arguments against the use of predictive genomic testing are typified by the statement, “testing punishes a person for the possibility that they might one day get sick.”41 Ambiguity arises because most common diseases involve multiple genes and environmental interactions. This is consistent with the concept of penetrance, or an individual’s risk of developing the disease when carrying a mutated gene.42 Typically, diseases resulting from a SNP are highly penetrant whereas those from multiple mutations express reduced penetrance. Undoubtedly, many qualified individuals could be passed over for accession if genomic testing was

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40 Guttmacher, 2.
41 Krumm, 509.
implemented without accounting for these variables.

The AFMS must establish a policy that integrates genomic medicine into the accessions process but precisely controls its use. Defining the policy in advance would prevent military abuses like those previously committed in the civilian sector.\textsuperscript{43} However, the purpose of a policy allowing accession-level genomic screening must not be simply saving money. The policy must be two-fold, protecting the privacy and rights of potential Airmen while allowing the Air Force to identify with high confidence those who have conditions excluded by DoDI 6130.03.

Any policy protecting current and potential Airmen will likely take the approach used by Congress, implementing both privacy-based and antidiscrimination features. Although the equality-based paradigm is most comprehensive it argues that there is no genetic norm, therefore there is no such thing as abnormal. That approach is internally inconsistent with current practices that exclude individuals for a variety of conditions, which include some that are known to be genetic in origin.

One method for implementing accession-level genomic screening would be through establishment of a Surgeon General-sanctioned, accession-level, genomic-screening board (ALGSB). The ALGSB would use evidence-based recommendations from independent sources to support genomic screening and identification of conditions disqualified by DoDI 6130.03. It would only exclude individuals from military service for diseases that could foreseeably render an Airman unfit during a 20 year career. Setting the standard of disease onset at 50 years of age would meet this intent. For example, an individual at risk for Parkinson’s disease would not be excluded from service since usual onset is after the established age cut-off of 50. Conversely, an individual at risk for a psychiatric disorder would be excluded if the usual age of onset is 50 or

\textsuperscript{43} Krumm, 501.
under. However, these actions would be predicated on the ALGSB having high confidence in genomic tests to accurately, consistently and quantitatively assess risk.

The Evaluation of Genomic Applications in Practice and Prevention (EGAPP) working group is one example of an independent, public group working in this area. The Centers for Disease Control Office of Public Health Genomics established EGAPP to evaluate “genetic tests and other genomic applications for clinical and public health practice in the United States.”

Their process involves a systematic review of available literature to make clear recommendations as to the clinical validity and utility of genomic tests. In short, they identify genomic tests with published documentation substantiating effectiveness at determining susceptibility to common disorders (e.g. heart disease, diabetes), drug-related adverse events and disease prognosis. Importantly, EGAPP has not yet substantiated the clinical validity and utility of any genomic tests. While EGAPP assesses genomic diseases the NIH office of Rare Diseases Collaboration, Education and Test Translation Program evaluates tests used for screening single-gene disorders.

An Air Force accession-level genomic screening program using only sanctioned tests and recommendations from an independent public organization would have more legitimacy than a program using internally generated standards. Further, it would make accession-level genomic screening consistent with medical-based screening through use of common standards. Finally, defining genomic screening parameters would enable the AFMS to better identify and screen out individuals not meeting DoD standards. Parameters would include confining disqualifying

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conditions to those already in DoDI 6130.03 and further restricting to conditions that could foreseeably affect an Airman during a 20 year career.

While the above discussions focused on the use of genomic information in accession screening and clinical medicine, at least two additional uses for this information are likely and will require AFMS policy guidance. First, the Air Force’s large genomic data warehouse and electronic record could be used to detect gene-disease associations. New assays are identifying variants about which little, if anything, is known. A large cohort of patient health data linked to genomic information could be invaluable to determine the significance of these findings. Second, forensic investigations currently use DNA, dental, and other biometric data. A policy regarding the release of samples or sample analysis must be developed consistent with legislation governing the DoD DNA repository.46

### Inherent Risks of Genomic Information

In spite of its value, storing genomic information introduces risks to the AFMS. Ongoing research is sure to define further associations between disorders and their genomic origins which could create an AFMS duty to periodically reanalyze this information and identify at-risk patients who may require medical care. The resulting workload from reanalysis could grow exponentially as more patient data is acquired and stored. Because the AFMS may not be able to locate some of the at-risk patients, clinic and provider responsibilities must be defined in policy and be accompanied by procedural guidelines. Further, the AFMS must establish a policy and process for reanalysis of stored genomic data to accommodate new gene-disease discoveries. There will also be a requirement to develop information systems to support the reanalysis.

Again, testing standards adopted from an independent-civilian organization like EGAPP

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would be more understandable for the patient and credible for the AFMS. As with all medical testing, only genomic tests whose beneficial impacts exceed their harmful ones should be adopted, including limiting tests to those associated with improved outcomes and quality of care. Further, adopting clinical practice guidelines would support providers in determining how to best use and present genomic information when discussing it with their patients.

Additionally, as the body of case law grows, the responsibilities of medical providers will conceivably change in response. At this time it is not possible to project the direction that this will go. However, “failure to anticipate what may become standard of care could result in these issues being decided through malpractice litigation.” For instance, in the limited number of cases thus far “the courts have affirmed a physician’s legal responsibility to warn family members.” Policy must address how to notify family members of their risk when the patient does not consent.

Finally, the Feres Doctrine, as long as it remains recognized by the courts, precludes legal risks to the AFMS as a result of treating active duty members. This would provide some protection to the AFMS against risks associated with storing genomic data for active duty personnel. Unfortunately there is marginal value in that since genomic information would be stored for all patients if the standard required it.

Data Storage, Ownership, Disclosure and Disposition

The above discussions focused on use and misuse of genomic information but also important are the administrative issues surrounding how the information is stored and protected.

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47 Botkin, 228.
48 McGuire, Personal Genomics, 1687.
49 Raby, 12.
50 Peshkin, 4,
51 Lt Col Dan Olson, telephone interview by author, October 13, 2010.
Procedures to safeguard genomic information must be defined, to include a determination by policy makers of whether safeguards extend only to the entire genome sequence or also to its component pieces. If it extends to the component pieces, the policy must define how much of the sequence must be present for the safeguards to apply. In addition, HIPAA established that patients’ own their health record data. Thus, a policy governing AFMS use of genomic data should incorporate patient preferences for disclosure and release of information to civilian providers (upon referral), TRICARE, and other business partners. Active duty Airmen may not have a choice whether their genomic information is used in their care but they do have a right to control its disposition when they separate or retire. Further, non-active duty patients must be able to opt out of genomic screening, with accompanying education on standard of care, and should also control disposition of their information upon leaving AFMS care.

**Personal Genomic Testing**

In spite of questionable merit, personal genomic testing is now offered direct to the public. The testing produces vague reports for the patient similar to those from whole body CT scans. Current literature advises against personal genomic health screenings because they have marginal value and the FDA presently does not regulate most testing. Therefore, the AFMS must establish a policy restricting a provider’s responsibilities to patients who undergo personal testing.

The literature expresses valid concerns of a “cascade effect” of “worried well” seeking follow up, driving up health care system costs or limiting resources available for legitimate

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52 Ojha, 387.
Because of their uncertain clinical validity and utility, personal genomic tests place providers in the position of wondering how to respond. Moreover, providers must be able to explain to patients what is known and unknown about the testing, knowledge they may not have if they did not order the test.

**Education**

Ultimately, both patients and providers will require education. Genomic data is inherently complex and providers “need to understand genetic variability, its interactions with the environment, and its implications for patient care.” Therefore, education must start with medical personnel. It includes pre-test counseling to impart a general understanding for the meaning of test, followed by post-test education for patients and families which must address inheritance, disease management (including required additional treatment or monitoring), prevention, implications for family, resources and research. Patient education must generally “promote informed choices and adaptation to the risk or condition.” The value of education cannot be overstated if for no other reason than because patients are more compliant with prevention activities after being counseled on genetic risk.

Equally important to educating a patient on test results is addressing their right not to know. This is not an uncommon request. For instance, Dr James Watson didn’t want to know his Alzheimer’s risk when he was given his personal genome and 40% of women at high risk for breast cancer opted out of genetic testing, presumably because they also did not want to

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55 McGuire, Unwelcome Side Effect, 2669.
56 Guttmacher, 1515.
57 Raby, 7.
58 Frezzo, 88.
59 Krumm, 506.
60 McGuire, Personal Genomics, 1687.
The AFMS must create both policy and guidelines to address patient and family members’ right not to know. Undoubtedly, planning for and delivering comprehensive patient education may be more involved than the actual testing process.

**RECOMMENDATIONS:**

The AFMS should consider implementation of the following recommendations prior to widespread integration of genomic medicine into accessions and practice.

1. Since active duty members are largely excluded from legal protections that civilians enjoy, the AFMS must draft a comprehensive policy to accomplish the following:
   a. Establish GINA-like protection for active duty members.
   b. Differentiate between disparate safeguarding requirements for genetic vs. genomic information. Genetic information is protected health information but genomic information should receive additional protection.
   c. Define information storage, disclosure and disposition processes. Storage must include protection of genomic information as discussed above. Additionally, processes must be established for disposition of genomic information when active duty and non-active duty leave AFMS healthcare.
   d. Implement a notification process which also accommodates requests not to know. The process must also define responsibility for dealing with patients that cannot be located.
   e. Establish role of genomic information in research and forensics.

2. Healthcare workers are on the front lines of genomic medicine. The AFMS must educate them so they, in turn, can properly practice genomic medicine and educate their patients.

3. Craft information technology solutions to protect and manage genomic information, including

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Wade.

Peshkin, 4.
reanalysis of stored information for new gene-disease associations. Implementing technology-aided solutions for rescreening genomic information is critical for the AFMS to accomplish its duty in meeting a potential future standard of care.

4. Conduct a legal review on the implications of accession-level genomic screening.

5. The credibility of accession-level genomic screening hinges on the perception of fairness to accession candidates. Hence, the AFMS must select standard-setting organization(s) from which to adopt standard(s) of care, e.g. EGAPP.

6. Integrate genomic medicine into AFMS healthcare delivery and accessions. The benefits of genomic medicine will drive it as the standard of care.

**CONCLUSION**

Several conclusions emanate from the preceding analysis. First, differentiation must be drawn between genetic and genomic information. Genetic information has been a growing part of medicine for decades and is adequately protected by HIPAA and existing AFIs. Conversely, genomic information, defined in this paper as the entire human genome sequence or an agreed upon component, is unique because it yields unprecedented insight into an individual. Further, prescient thinkers could imagine novel ways it could be exploited or misused. Therefore, it warrants new, specific protection. Second, because of its newness genomic medicine is yet to be comprehensively addressed by policy. Thus, the AFMS must produce new policy that defines and governs the field in which genomic medicine will be practiced. Third, opportunity exists within the accession process to integrate genomic medicine to improve new accession screening. This should include adoption of standards from an independent, civilian organization like EGAPP. Also within the realm of accession screening, genomic medicine has the potential to identify and exclude recruits who will develop disqualifying diseases in the future. Accession-
level genomic screening is the logical companion of genomic medicine. However, its use must be prescribed now so it is not inappropriately used in the future. Moreover, it must be limited to conditions defined in DoDI 6130.03 and its application should be restricted to a disease age of onset that corresponds to the end of a 20 year career.

Availability of genomic information is ushering in a new age of medicine along with accompanying privacy, discrimination and legal risks. Acting now will allow maximal guidance from AFMS leadership before genomic screening becomes institutionalized. Proactive steps will protect both Airmen and the Air Force and could avert future problems due to misuse or inappropriate disclosure of genetic information. Genomic medicine is the future and it is here. Now is the time to address the realities it brings.
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42. United States. *United States Code*: Military Departments. Title 5, Part 1, Chapter 1, Sec. 102.


