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THE PROMISE AND PERILS OF PERSONALIZED MEDICINE

Rear Admiral Susan J. Blumenthal, MD, MPA (ret.) and Praveen Pendyala

AND MORE >>>

The Promise and Perils of Personalized Medicine

>>> *Rear Admiral Susan J. Blumenthal, MD, MPA (ret.) and Praveen Pendyala reflect on the implications of recent advances in personalized medicine and the policies that are needed going forward.*

The completion of the Human Genome Project in 2003 marked one of the most significant scientific achievements in human history. The 15-year project successfully sequenced the 3.3 billion base pairs of nucleotides in the human genome, fulfilling a global scientific quest to map the building blocks of human life—that is, genes—and opening up the door for the development of molecular diagnostics and targeted treatments for diseases that comprise a new frontier in health care. Genome wide association studies (GWAS) have explored genetic diversity among human beings, already revealing statistically significant correlations among over 800 sequence variations known as single nucleotide polymorphisms (SNPs) and 150 clinical phenotypes or diseases.¹ This newly expanded genetic knowledge base is ushering in an era of “personalized medicine,” in which an individual’s unique genetic profile is being used to guide preventive and therapeutic interventions as well as to determine sensitivities to drugs and environmental exposures. Clinically relevant genetic characteristics such as mutations and expression patterns are captured by the over 1,600 molecular diagnostic tests currently available today.² Cutting edge predictive genetic tests that assess an asymptomatic person’s predisposition to a disease can help an individual take action to prevent illness by addressing that illness’s risk factors. For example, women who test positive for a deleterious mutation in the BRCA1 or BRCA2 genes, mutations which increase susceptibility to breast cancer by 40-80% over a lifetime, may be more likely to pursue protective actions such as limiting estrogen exposure, taking preventive medications, reducing alcohol consumption, increasing physical activity, and in some cases, choosing prophylactic mastectomies.³ Despite reflecting major advancements, information resulting from the use of genetic screening has also opened up a Pandora’s box of daunting ethical and legal issues and unanswered questions about how to define ownership of genetic information, how to protect it from improper use, and whether physicians have a duty to warn their patients’ relatives about hereditary risk of disease.

History and Legislation

According to the principle of “genetic excep-

tionism,” genetic test results are classified as highly personal health information.⁴ As compared to other types of clinical data, genetic profiles are immutable and can uniquely identify individual patients. To the alarm of patients and policymakers, researchers have demonstrated that it is possible to work backwards from a common pool of de-identified genetic information and identify individuals within a database.⁵ Some also believe that genotypic information is distinct from other health information about individuals, such as body weight or cholesterol-LDL levels, because it opens a window into the specific future health risks of currently healthy people. Because of the sensitive nature of genetic test results, patients are concerned about who may have access to and ownership of their genetic information. Many patients’ desire to preserve ownership and confidentiality of their genetic test results springs from fears that their genetic information could serve as a basis for discrimination by third parties such as insurance companies, employers, or even relatives. Successfully integrating potentially life-saving molecular diagnostic tests into clinical practice in a way that ensures the privacy and confidentiality of a patient’s genetic information represents one of the most significant policy and ethical challenges today.

In 2008, Congress took a major step forward in the advancement of personalized medicine with legislation protecting genetic information and safeguarding privacy in the passage of the Genetics Information Non-discrimination Act (GINA). The enactment of GINA signifies a landmark achievement because it prohibits employers and health insurance companies from discriminating against individuals on the basis of genetic information. GINA prevents employers from using genetic information as a factor in making hiring, firing, job placement, and promotion decisions. GINA also makes it illegal for health insurance companies to deny coverage, rescind policies, or raise insurance premiums based on the results of a genetic test. The legislation was hailed as “the first major new civil rights bill of the 21st century.”⁶

Unfortunately, the passage of GINA was only a partial solution for alleviating the privacy concerns associated with genomic medicine. It does not protect patients from discrimination by entities other than employers and health insurance companies, such as long-term care, disability, and life insurance firms. This means that, despite the passage of GINA, life insur-

ance companies can still deny coverage to a 40-year-old woman on the basis of a positive test for a breast cancer gene mutation. Fortunately, many states have stepped in to fill the gaps in GINA. 16 states have adopted laws to bar life insurance companies from denying coverage on the basis of genetic information. 16 states have also provided patients with protection against discrimination by disability insurance companies, and 10 states have prohibited genetics-based discrimination by long-term care insurance companies.⁵

Two Models for Confidentiality

Genetics-based discrimination by employers and insurance companies are not the only things patients fear. Some patients also want to keep their genetic information private from family members. The most common reasons for a patient’s resistance to disclosing genetic test results are fear of stigmatization, blame, and pre-existing tensions with family members. This concern on the part of patients opens up a new dilemma for clinical care. Do physicians have a duty to warn a patient’s relatives of their potential risk for a hereditary disease, despite the patient’s not wanting to disclose personal information to family members? The answer to how a physician should balance patient privacy with the health care of relatives when handling genetic information depends on the particular model of confidentiality applied. According to the “personal account model,” genetic information is the sole property of the patient, and patient confidentiality is absolute.⁷ Therefore, a physician would not be able to warn relatives of their risk of certain diseases based on genetic factors unless the patient provided explicit consent for disclosure. The personal account model is supported on the grounds that patients are willing to undergo genetic testing in the first place because of the complete assurance of confidentiality. If confidentiality becomes conditional, then the basic level of trust underlying the physician-patient relationship is jeopardized.

Another framework of confidentiality, “the joint account model,” takes a different view.⁷ According to this model, a patient’s genetic information is the property of the family, and all relatives who are deemed “account holders” should have access to the genetic test results of a relative.⁷ Therefore, if necessary, a physician may override the patient’s confidentiality to directly inform family members of their risk of a genetically-based disease. The joint account model is built upon a belief system that places the health of the family above the need for protecting an individual patient’s confidentiality. The 2002 report of the Human Genetics Commission promotes “genetic solidarity” and “altruism” as fundamental values of the joint account model.⁸

Legal Issues

Despite the widespread prevalence of the personal account model in the practice of medicine, the joint account model is not completely alien to clinicians and is already applied in certain spheres of health care practice. Physicians are required to report communicable infectious diseases such as syphilis and TB, gunshot wounds, domestic violence, child abuse, and imminent life-threatening behavior, regardless of a patient's desire to keep the incident or information confidential. In *Tarasoff v. Regents of the University of California*, the Supreme Court of California declared that a university psychotherapist should have taken reasonable actions to prevent the murder of Tatiana Tarasoff after a fellow graduate student at UC Berkeley confided in the psychotherapist of his intention to kill Tatiana. The landmark ruling set the stage for the establishment of the "Tarasoff doctrine," according to which a physician is expected to breach patient privacy and confidentiality if "the patient poses a serious danger of violence to another."^{9,10} Studies also demonstrate that use of the joint account model with its emphasis on the physician's interaction with the family is effective for increasing testing rates among "at risk" relatives. For example, while only 36% of family members opted for BRCA testing when informed by a relative that they carried the genetic mutation for breast cancer, 56% of family members underwent BRCA testing when they were directly informed of a possible hereditary risk by clinicians.¹¹ The question of which model of confidentiality should be adopted by physicians, though, is far from settled as case laws, statutes, regulations, and medical professional organization recommendations are often at odds with each other.

The verdicts of a few noteworthy legal cases suggest that the courts are slowly moving towards increasing physician responsibility to protect the health of patients' relatives. The first case that confronted the ethical dilemma between absolute adherence to patient confidentiality and physician duty to warn relatives of genetic disease was *Pate v. Threlkel*.¹² In 1987, the mother of Heidi Pate was diagnosed with hereditary medullary thyroid carcinoma but was not informed by physicians that the disease was heritable and could affect her children. Three years later, Heidi Pate was also diagnosed with the disease and sued her mother's physician on the grounds that if she had been

informed earlier of her risk, she could have taken the necessary measures to prevent the onset and progression of the disease. The Florida court declared that physicians had a duty to warn relatives of their risks of inheriting a genetic disease and specified that the duty was satisfied by educating patients about the familial implications of a genetic disorder and encouraging patients to share genetic test results with relatives if necessary or whenever possible.

In 1996, the court in *Safer v. Estate of Pack* advocated for an even more expansive "duty to warn."¹² Donna Safer's father died from colorectal cancer that had metastasized to the liver, and her father's physician failed to inform him of the genetic component of the disease. He had suffered from familial adenomatous polyposis (the presence of hundreds of colon polyps in childhood) that inexorably leads to colon cancer. 26 years later, Donna Safer was diagnosed with colorectal cancer. She sued the estate of Dr. Pack, claiming that if she had been told of her elevated risk, she could have taken actions to prevent progression to metastatic cancer. Prophylactic colectomy in late adolescence is the intervention of choice although recent studies suggest certain anti-inflammatory medications might also be helpful. In this

law suggests that physicians may be legally permitted but not legally mandated to breach confidentiality and inform relatives of a genetic risk if the relative is in danger of developing a life threatening yet preventable disease. On the contrary, while case law seems to provide physicians with flexibility in overriding patient confidentiality to protect family members, statutory law narrows that room for discretion.

Unlike the courts, Federal and State legislative policy strongly promotes the application of the personal account model of confidentiality in medical practice and genome medicine. The Standards for Privacy of Individually Identifiable Health Information (Privacy Rule) of the Health Insurance Portability and Accountability Act (HIPAA) passed by Congress in 2003 requires physicians and other health care providers to protect against the unauthorized disclosure of individually identifiable health information including genetic information under threat of civil or criminal penalties. However, this privacy rule also includes "public interest exceptions" to the strict nondisclosure policy. For example, physicians are allowed to share personal patient information if "there is a serious and imminent threat to a person or third party" and if

the physician has the capacity to avert serious harm.¹⁴ Law enforcement cases and infectious diseases are examples of circumstances in which physicians are allowed to breach patient confidentiality under HIPAA. It is unclear whether the predisposition for a genetic disease, such as medullary thyroid carcinoma, constitutes a "serious and imminent" threat for a relative, which, therefore, would fall under the public interest exception of the privacy rule. Currently, many in the medical establishment disagree with the notion that a genetic disease risk should be classified as a public interest exception to HIPAA because the



actions of the patient will not affect a relative's possession of a deleterious genetic mutation.¹⁴ Also, genetic privacy laws passed by the states aim to uphold the personal account model of confidentiality by prohibiting the disclosure of genetic information without explicit permission by the patient. For example, Alaska's statute states that "a DNA sample and the results of a DNA analysis performed on the sample are the exclusive property of the person sampled or analyzed."¹⁵ 27 states have passed laws that require patient consent to disclose genetic information.¹⁶ California even imposes criminal penalties on physicians for disclosing genetic test results to third parties without the written

case, the court reinforced the decision of *Pate v. Threlkel* that physicians are obliged to warn patients' relatives of their risk of a genetic disease. While the trial court ruled in the favor of Dr. Pack on the basis that the physician did not share a special relationship with the patient's relatives, the appellate court reversed the decision and recognized that physicians have a responsibility to directly notify relatives, including children, if informing them through the patient is not feasible or effective, and must take "reasonable steps" to do so.¹³ However, the court did not define what constitutes "reasonable steps" so the precise manner in which the duty to warn should be discharged still remains ambiguous. A review of recent case

consent of the patient.¹⁷

Organized Medicine’s Perspective

In addition to judges and legislators’ rulings on this issue, professional medical associations have also offered guidance to clinicians about how to handle the genetic information of their patients.¹⁷ Several medical professional societies have published reports outlining how physicians should reconcile their duty to preserve patient autonomy (respect for patient privacy), the cornerstone of the doctor-patient relationship, with their commitment to beneficence (doing no harm or a duty to warn). In general, recommendations from health professional organizations including the American Medical Association (AMA) and the American Society of Clinical Oncology (ASCO) are consistent with the policy issued by the Florida court in *Pate v. Threlkel*.¹⁸ These organizations stress the fundamental importance of upholding patient confidentiality by asserting that while physicians may have a duty to warn relatives of a genetic risk factor for

a hereditary disease, it is the patient who must serve as the gatekeeper of that genetic information. According to the AMA and ASCO, physicians should use the personal account model and never breach patient confidentiality in dealing with genetic information. Rather than permitting physicians to contact family members directly, the recommendations of these organizations emphasize that physicians have a duty to counsel and empower patients to communicate genetic risk information directly to their relatives. For example, ASCO advises oncologists to “remind patients of the importance of communicating test results to family members” and concludes that “the cancer care provider’s obligations (if any) to ‘at risk’ relatives are best fulfilled by communication of the familial risk to the person undergoing testing.” The AMA’s position is that physicians should “make themselves available to assist patients in communicating with relatives to discuss opportunities for counseling and testing, as appropriate.”¹⁴ Both organizations underscore that the education of the patient on the familial implications of a genetic disease must be carefully documented in the medical record as a part of the informed consent process.¹⁴

Alternatively, the 1998 guidelines proposed by the American Society of Human Genetics (ASHG) and the 1983 report of the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research are more closely

aligned with the joint account model. They suggest that medical geneticists should be permitted to breach patient confidentiality but only under certain circumstances. According to ASHG and the President’s Commission, physicians can disclose genetic risk information to relatives without a patient’s consent if each of the following conditions have been met: (1) there is a high likelihood of harm if the relative is not warned, (2) effective interventions are available to prevent or treat the disease, (3) harm of nondisclosure outweighs harm of disclosure, and (4) relatives at risk are identifiable.^{19,20}



For example, under this set of criteria, it would be inappropriate for physicians and other health providers to disclose genetic information about a patient to his or her relatives at risk for Alzheimer’s or Huntington’s disease, conditions which lack effective preventive interventions at this time, but might be appropriate for breast cancer, for which there are evidenced-based preventive measures, including medications such as tamoxifen as well as prophylactic surgical interventions.

Future clinical practice guidelines addressing access to and confidentiality of genetic information must also reflect the values and experiences of the clinicians on the frontlines of genetic medicine. Research has revealed a striking dissonance between physicians’ personal attitudes regarding the duty to warn relatives of genetic risks of disease and the actual actions taken by clinicians when confronted with this ethical dilemma. According to one study, 69% of medical geneticists believed that they have a duty to warn relatives, 25% of medical geneticists had considered breaching patient confidentiality to notify relatives, and 3% actually did so.²¹ In another survey, 21% of genetic counselors had strongly considered breaching patient confidentiality to warn relatives at risk for a heritable illness, but only 0.84% of respondents actually ignored their patients’ wishes not to disclose genetic test results.²² The discrepancies between the internal beliefs and actual actions taken by genetic medicine practitioners and counselors may illustrate the broader tension between a physician’s

commitment to his or her individual patient and the broader public health considerations.

The Patients’ Perspective

The feelings and beliefs of the most important stakeholder—patients—should be at the forefront of any policy discussion regarding the disclosure of genetic information. Research demonstrates that patients with a hereditary disease overwhelmingly believe that their relatives have a right to be informed of any genetic risks. For example, in one study, the vast majority of patients (70%) expressed that children should be warned if their parents test positive for a genetic condition. This finding is consistent with an observation made by one physician: “my impression from my own practice and from talking to colleagues is that family members rarely refuse to disclose information about shared risk to their relatives.”¹¹ While the majority of patients want relatives to be aware of possible genetic risks, 92.7% of participants in a recent study believed that the duty to inform relatives at high risk of a genetic disease rests with the

patients themselves, not with physicians. Participants in the same study largely agreed that the confidentiality of genetic information is absolute and believed that physicians should never disclose genetic information to relatives without the explicit approval of the patient. 71.8% of the patients were uncomfortable with physicians sharing genetic test results with relatives without their permission and over 50% of participants believed that physicians should be punished if they did so. In fact, 80% of patients in the study advocated for the establishment of laws to prevent physicians from breaching the confidentiality of patients’ genetic test results under any circumstance.²³ The reality that patients are willing to disclose genetic information to protect relatives yet want their physicians to adhere to the personal account model of confidentiality, requires that strategies in the short term focus on equipping patients with the knowledge and skills necessary to effectively inform family members who are at risk. However, it is advisable that physicians and genetic counselors make themselves available to facilitate a dialogue between patients and their relatives if patients do not feel capable of communicating this information on their own.

Realizing the vision of personalized medicine will require us to confront head-on the complex ethical and legal considerations posed by genetic testing as well as address how to handle the ever expanding body of genetic information stored in clinical data-

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bases. Despite the passage of GINA in 2008, ethical issues surrounding third-party access to genetic test results and data bases remain unresolved. While GINA defined parameters restricting employer and health insurance companies' access and use of genetic information, the rights to this information by other third parties including life insurance firms and, most importantly, a patient's relatives remain unaddressed. The ambiguity over whether genetic information should be treated as personal medical information in the traditional sense or familial information raises a dilemma between a physician's duty to protect patients' confidentiality and the duty to warn at-risk relatives.

Further Action is Needed

The maze of conflicting policies on the disclosure of patients' genetic information to family members has created a confusing landscape for physicians, medical geneticists, genetic counselors, and for patients themselves. For example, a clinician or counselor's decision to inform a relative at high risk for a serious but treatable genetic disease might be justified according to case law and ASHG recommendations but be considered a major infraction to a patient's confidentiality under statutory law and AMA practice guidelines. Other pertinent policy questions regarding the disclosure of genetic information remain unanswered, such as which members of a patient's family should be warned and the appropriate age at which a child should be told of a disease risk based on genetic test results. Clear, standardized guidelines across organizations are needed to ensure that patients' genetic information will not be abused nor their privacy breached, while minimizing the legal risk for clinicians, medical geneticists, and genetic counselors. As part of the informed consent process for genetic testing, physicians should discuss with their patients beforehand the circumstances under which they might feel obligated to share test results or encourage their patients to share information with relatives. These conversations should be documented in the patient's chart. The application of this type of provision, a genetic "Miranda warning," is controversial and will require further discussion, but for the time being, it can serve as an important safeguard.¹³ Furthermore, physicians who order genetic tests should have the knowledge and skills necessary to counsel their patients and their families regarding decision-making.¹² To foster such conversations, medical education must include a focus on genetic testing and counseling techniques. Additionally, practitioners should closely monitor updated ethical guidelines and emerging case laws on genetic testing issues.¹⁷ In an era of dramatic scientific advances, striking a balance between respecting patient privacy and confidentiality while minimizing harm to relatives will be vital to bringing the revolutionary tools of personalized medicine from the bench to the bedside. 

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