

Stanford researcher discusses new AHA call for tougher regulation of genetic testing

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Rapid advances in genetic disease research that are transforming how we diagnose and treat illness require new safeguards to protect patients from the misuse of these technologies and realize their full potential, according to new American Heart Association policy recommendations.

In an effort to keep pace with these changes, the <u>American Heart</u> <u>Association</u> issued today a set of policy recommendations that include federal oversight of <u>genetic testing</u>, a <u>prohibition</u> against awarding new <u>patents</u> for <u>gene discovery</u> and stronger rules to protect against discrimination based on a person's genetic profile.

The recommendations, which focus on heart and blood vessel diseases, were published in the journal Circulation. They were written by a panel of cardiologists, pharmacists, nurses, genetic counselors and other medical professionals over a two-year period of research and discussion.

"The <u>safeguards</u> are essential for patients in a new age of medicine," said Euan Ashley, MD, assistant professor of cardiovascular medicine at the Stanford University School of Medicine and chair of the policy statement writing group. "It is no longer far-fetched to imagine a world where every patient's genome is in their medical record. The doctor might be able to simply look it up when prescribing medication. This very rapid change in technology provides a tremendous opportunity, but also presents a challenge in being responsible with that information."

Genetic information arises from many technologies that themselves are



rapidly evolving. It is, by its very nature, complex. Without appropriate training of medical professionals and adequate patient protections, there are risks this information could be misused, misinterpreted or not used to its full potential.

Genetic tests

In one of its key recommendations, the panel calls for federal oversight of genetic testing, including those tests being marketed directly to consumers, and identifies the U.S. Food and Drug Administration as an organization well-placed to lead their evaluation and approval. "All genetic tests, including laboratory-developed genetic tests, should undergo independent review to confirm their analytic and clinical validity," the policy paper states, noting that the results should be made public.

Controversy over the validity of certain genetic tests prompted the panel's concern about the possible need for oversight, Ashley said. Debate over the validity of genetic testing has been ongoing for the past decade with concerns that results of certain tests given to consumers were "medically unproven, meaningless and misleading," according to a report from the U.S. Government Accountability Organization.

Most recently, hearings before the Congress in 2010 explored allegations of questionable practices by direct-to-consumer genetic testing companies. In conjunction with those hearings, the GAO produced its report, "Direct-to-consumer genetic tests: Misleading test results are further complicated by deceptive marketing and other questionable practices."

A review of the history of the misuse of genetic testing supports the need for greater involvement by the FDA to ensure efficient test reviews, the paper states. The agency's statutory authority, scientific expertise and



experience in regulating genetic tests make it well-suited to this role.

Patenting of genes

The policy paper also takes a firm stand on the ethically charged and commercially important question of whether genes can be patented. The authors recommend that the current practice of patenting gene discoveries should no longer be allowed because it involves "observation," not "invention."

"You shouldn't be able to patent something that is part of nature," said Ashley. The paper's authors point to a case now before the U.S. Supreme Court of a company, Myriad Genetics, which holds the patent on two genes — BRCA1 and BRCA2 — that are linked to increased breast and ovarian cancer risk. The company now has a monopoly on the test related to these genes, which costs more than \$3,000, and some believe this monopoly prevents many women from getting the test. The patent on the genes also prevents other laboratories from performing similar tests and may hinder research involving these genes.

"Further patenting of DNA sequences should not be approved where the 'invention' involves only the observation of functionally unaltered human DNA," the paper states.

Anti-discrimination legislation

In addition, the panel recommends stronger federal laws to ensure that undergoing genetic tests does not lead to financial penalty or other types of discriminatory treatment.

Although the 2008 Genetic Information Nondiscrimination Act protects people against genetic discrimination by health insurance companies and



employers, it does not protect against the possibility of long-term care, disability and life insurance providers withholding coverage from those who have been diagnosed with a genetic disease, such as congenital heart disease.

Other recommendations

The paper also calls for:

• New billing codes to facilitate reimbursement for genetic tests. Current insurance billing practice relies on the provision of a code that indicates an abnormal symptom or sign for the patient. The problem is that the decision to ask for a genetic test often is based on information from other family members, not the patient. The current system doesn't provide an adequate mechanism for reimbursement for screening at-risk relatives.

• An increase in the number of genetic counselors who specialize in helping patients understand and adapt to the implications of the genetic contributions to disease. The number of people being assessed for hereditary diseases and predispositions is likely to increase as more genes associated with disease are uncovered. More funding for genetic counseling training programs is needed as well as improvements in reimbursement for these necessary services.

• Increased funding for clinical research in genetics.

• More training in genetics and genomics for health-care professionals. These new technologies will generate an enormous amount of patientspecific genetic and genomic information, much of which will be completely new to the practicing clinician. Genetics and genomics should be included as a fundamental part of the training curriculum for all medical practitioners.



"Health-care workers are just a bit scared about genetics and don't know what to do with it," Ashley said. "Anyone can spit in a cup and get a genetic test result in the mail, but most medical professionals wouldn't know what to do with the results. We believe these new technologies could really transform how we practice medicine, and as health-care professionals we need to be prepared."

Provided by Stanford University Medical Center

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