

# Safeguards against misuse of genetic data urged

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Rapid advancements in genetic disease research necessitate innovative safeguards for patients, according to new American Heart Association policy recommendations published in *Circulation*, an American Heart Association journal.

Recent scientific progress includes the mapping of the entire [human genetic code](#), or [genome](#), which was completed in 2003, and new accelerated [gene-sequencing](#) techniques. These discoveries have led to cheaper, more readily available genetic tests, but regulations have lagged behind.

"The potential of the new technologies is incredible," said Euan A. Ashley, M.R.C.P., D.Phil., chair of the policy statement writing group and assistant professor of medicine in the Cardiovascular Division and director of the Center for Inherited [Cardiovascular Disease](#) at Stanford University School of Medicine, in Stanford, California.

"Genetic testing provides a tremendous opportunity but also a challenge in being responsible with that information," Ashley said. "If the information is available, how best do we use it to really improve care for individual patients?"

Focusing on heart and blood vessel diseases, the policy statement recommends:

- Stopping the practice of awarding patents for observing a gene

In the modern era, gene sequencing simply involves observation of the natural world and not invention, therefore genes should not be patentable. The investigators cite a controversial case, now before the Supreme Court, of a company that patented the two primary genes — BRCA1 and BRCA2 — linked to an increased breast and ovarian cancer risk. The company has a monopoly on testing related to these genes and some believe this monopoly has reduced access to this test for women.

- Establishing federal oversight of genetic tests

All genetic tests should be regulated for quality. The Food and Drug Administration (FDA) is well suited to this task because it has statutory authority, scientific expertise and experience in regulating genetic tests.

- Expanding anti-discrimination legislation

There are no protections against genetic discrimination by long-term care, disability and life insurance providers. To maximize the health benefits of genetic testing, federal laws should ensure that patients can undergo such testing without financial or other penalties.

The 2008 Genetic Information Nondiscrimination Act (GINA) prohibits discrimination based on genetic information by health insurance companies and employers but does not prevent insurance companies from withholding coverage from patients who have already been diagnosed with a genetic disease such as congenital heart disease.

Provisions in the Affordable Care Act, which will be fully implemented in 2014, will require group health plans and issuers of health insurance to

provide coverage for all people who request it, regardless of their genetic profile and health status.

Recommendations also include:

- [Genetic testing](#) and counseling in specialized centers;
- Reimbursement codes for screening of family members of those affected by genetic disease;
- Increased funding for clinical research in genetics;
- More studies on the genetic link to heart and blood vessel disease risk;
- Genetics education for healthcare providers and patients;
- In-depth studies of genetically mediated responses to drugs, or pharmacogenomics, accompanied by expert consensus before changing prescription information.

The new proposals are the result of an expert panel of geneticists, physicians, nurses, genetic counselors and other medical professionals analyzing, discussing and reaching consensus on genetic research and testing practices over a two-year period.

"The [safeguards](#) are essential for patients in a new age of medicine. This is an unbelievable time in genetics," Ashley said. "The pace of change has been astounding. You can imagine a world now where every patient might have their genome in the medical record, and the doctor might be able to simply look it up when prescribing medication."

Provided by American Heart Association

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