

Genetic Tests Pose Tailored Care

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One of the nation's leading management companies of pharmacy benefits aims to confirm whether genetic testing can help eliminate the life-threatening and costly complications that many patients develop after starting a prescription of the anticlotting drug warfarin.

The collaboration between Medco Health Solutions Inc. and the Mayo Clinic on a study of warfarin users is one of the latest corporate forays into the emerging science of so-called personalized medicine, in which physicians use genetic or other molecular tests to tailor a patient's treatment.

Those promoting personalized medicine say the science boils down to delivering the right treatment at the right dose to the right patient at the right time, which they say could make health care safer, more efficient and cost-effective. Doctors might use genetic tests to customize the dosage of a drug such as warfarin, determine which treatment would work or pose safety problems, or find a patient's susceptibility to a disease.

Such customized therapy already has been put to some clinical use (some cancer treatments, for example, target certain genes or proteins) and drug makers, biotech companies, medical institutions, testing laboratories and government agencies such as the Food and Drug Administration and the National Institutes of Health appear eager to advance the practice. Health insurers are watching with interest.

"I think this is an explosion about to happen," said Robert Field, chairman of the health policy and public health department at the University of the Sciences in Philadelphia. "Five or 10 years ago, this was the promise of genetic technology. Today, we are seeing the first applications. I think five years from now, certainly 10 years from now, this will indeed dominate medicine.

"Personalized medicine would be able to tell us, through genetic markers, who's likely to respond positively and who's likely to respond negatively, before you even start the therapy."

That can have major implications: reducing or eliminating harmful side effects, saving patients from taking unneeded drugs and choosing therapies that fit a patient's genetic profile.

Such technology might save health insurers and others billions of dollars now spent treating life-threatening side effects or on drugs that don't help some individuals, or by preventing disease in patients found to be genetically susceptible.

This type of medicine also poses challenges, including changes in a pharmaceutical industry that has been based on blockbuster drugs rather than gene-oriented therapies aimed at smaller populations. Industry and government must answer questions about insurance coverage for new diagnostic tests and therapies, and about regulatory standards for these new drugs. Patient privacy is another concern; lawmakers in both houses of Congress have introduced bills to bar insurance and employment discrimination based on genetic data.

It is too early to say how big the overall savings might eventually be from widespread use of personalized medicine. The use of genetic testing to personalize dosages of warfarin, a half-century-old drug known by the brand name Coumadin, could reduce national health-care spending by \$1.1 billion a year, a recent study by the American Enterprise Institute and the Brookings Institution estimates.

Optimal doses of warfarin vary among patients, and the wrong amount can increase the risk of serious bleeding or stroke. The AEI-Brookings study estimates that formally integrating genetic testing into routine warfarin therapy could allow U.S. patients to avoid 85,000 serious bleeding episodes and 17,000 strokes annually.

Medco and Mayo Collaborative Services Inc. plan this year to evaluate the

potential of genetic testing on new users of warfarin, one of the most widely prescribed drugs in the U.S. Genetic testing can indicate how patients metabolize the drug, which may help doctors prescribe the right doses.

"It's no longer shotgun medicine; it's much cleaner," Medco Chief Medical Officer Robert Epstein said.

The Harvard Medical School-Partners Healthcare Center for Genetics and Genomics is recruiting 500 new warfarin users for a similar study. In November, the center hosted a personalized-medicine conference where representatives of Medco, insurer Aetna Inc. and biotech and major drug companies participated.

Trials showing the effectiveness of genetic testing for drugs like warfarin "would change dramatically for that drug how things are going to happen," said Harvard Medical School professor Raju Kucherlapati, scientific director of the Harvard-Partners center.

The science holds promise for new drugs and diagnostic tools aimed at cancer, heart disease and AIDS, as well.

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