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Personalized Medicine Battles for Acceptance and Funding

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In the last decade, personalized medicine has evolved into a complex field of diagnostics that are transforming patient treatment standards and promising to reduce the costs of health care. Before that, the phrase drummed up thoughts of a country doctor making house calls.

But the "personal" in personalized medicine refers specifically to recognizing patients as unique vessels that require unique treatments, as opposed to a one-size-fits-all approach. The field - an offspring of the human genome mapping - seeks through a blood test to isolate certain genetic traits that predispose patients to side effects or makes them more likely to benefit from particular therapies. By determining who does best on certain drugs, physicians save precious time once wasted on an age-old trial-and-error method. They spare their ill patients from false hopes and toxic reactions to drugs and procedures that, for them, reap no benefits.

The science is solid. But like a 90-year-old presented with an I-Pod, America's system of incentives and reimbursement is not equipped to understand it. The investment community, which is still recovering from the genomics bubble, is cautious to put money in an unproven field.

"This is nevertheless a very real phenomenon," said Edward Abrahams, executive director of the Personalized Medicine Coalition in Washington. "This isn't made up out of a pipe dream. There's a reality."

The reality is companies like Genomic Health Inc., of Redwood City, Calif., already have a product on the market. Oncotype DX, a multigene expression test introduced in 2004, can predict the benefit of chemotherapy for early-stage breast cancer patients and determine the likelihood of recurrence.

"When you talk about personalized medicine, there's a perception that it's kind of way off in the future, and the reality is it's here today," said Emily Faucette, director of corporate communications at Genomic Health.

Clinical studies published in *The Lancet* have shown that with a blanket treatment regimen, chemotherapy improves survival in only four out of 100 women with breast cancer.

"That's pretty amazing when you think that the treatment paradigm for years has been to treat almost all women with chemotherapy," Faucette said.

The concept of personalized medicine emerged in the late 1990s and has since grown to become a small industry all its own. In 2007, New York City-based Helix Health was formed as possibly the country's first personalized medicine practice, and several universities are now teaching it as part of their curriculums. Arizona State University and

the Translational Genomics Research Institute are building a medical school dedicated to the personalized medicine field.

The number of companies is unknown. The Biotechnology Industry Organization does not track them, partly due to a difficulty in classifying them. The non-profit Personalized Medicine Coalition was formed in late 2004 to heighten awareness of the field and to work with government to create a regulatory, reimbursement and incentive system that can accelerate the industry's adoption and growth. In three-and-a-half years, its membership has risen from 20 to 140 entities, which includes government and research institutions, health insurance companies, venture capital firms and about 65 biotech, pharmaceutical, diagnostic or tools companies. Among its members are Genomic Health, XDx Inc. and TheraGenetics Ltd.

XDx, of Brisbane, Calif., launched its first product, AlloMap molecular expression testing in 2005. It helps heart transplant patients avoid monthly endomyocardial biopsies in the first year that involve the painful insertion of biopsy shears into the jugular vein. The shears then are threaded through blood vessels to clip off small pieces of heart muscle in order to check for rejection. AlloMap uses gene-expression-based diagnostics to identify organ rejection through the draw of a peripheral blood sample.

A spin-off of the Institute of Psychiatry at King's College London, two-year-old TheraGenetics is developing TheraTest to identify the up to 50 percent of schizophrenic patients that do not respond to treatment, which for all patients costs about \$23 billion a year in the U.S.

For years, when treating patients, physicians have followed protocols of "if this doesn't work, try this" and have found themselves prescribing more drugs to counteract the side effects of the first drug prescribed. Meanwhile, patients live like lab rats and insurance companies cover the unnecessary therapies because that is how it's laid out in their policies.

"That's how medicine is practiced for the most part and that's how the regulatory and reimbursement systems are constituted," Abrahams told *BioWorld Financial Watch*.

"There's minimal emphasis on preventive care."

It appears to be an uphill battle for personalized medicine when its diagnostics are reimbursed according to a fee schedule that includes costly MRI tests and CAT scans. The current system reimburses according to the complexity of the test, not the value of it. "These tests are extraordinarily inexpensive in comparison to the value that can be derived from their performance," Abrahams said.

But if companies can't guarantee investors a respectable return, a field that shows huge potential will not thrive and patients will continue to receive an impersonal approach.

"To increase investment, we need to make certain changes so that the landscape is friendlier to personalized medicine," Abrahams said, "which, at the end of the day, promises better health outcomes for patients and lower costs for the system."

OncoType DX costs \$3,800, compared to an average for chemotherapy of \$30,000, a figure that can go up depending on the dose and regimen, as well as the additional drugs needed to treat the side effects, Faucette said. By using Genomic Health's test to identify the 96 out of 100 patients who won't benefit from chemotherapy, health care spending could be reduced for those patients by \$2.5 million.

Still, the company has worked hard over the last few years to gain acceptance by health insurers. The test is now covered for about 80 percent of all insured patients.

"That definitely was a challenge and continues to be a challenge," Faucette said. But despite the promise of personalized medicine for patients and diagnostic companies, drugmakers may feel their revenues threatened by tests that basically eliminate a large portion of their customers. It may be a growing pain that the industry must live through to reach a more profitable future where drug benefits are rarely in doubt.

"What's better - to have the drug not approved or to have it approved for a targeted population where there's high safety and high efficacy?" Abrahams asked. "That's the promise of personalized medicine from that point of view."

It's not all about eliminating therapies, either. Sometimes, these tests can help doctors pinpoint doses or spare patients from painful procedures, such is the case with XDX's AlloMap.

Scientists know that variations in CYP2C9 and VKORC genotypes are linked to the dose of the anticoagulant warfarin needed to treat patients effectively. A genetic test can now tell physicians who is a fast metabolizer and who is a slow metabolizer, enabling them to prescribe a dose of warfarin that minimizes the bleeding side effects, but is not too low that it fails to reduce a blood clot.

"All technology on the scene for personalized medicine is very promising," said Matt Gardner, CEO of BayBio, Northern California's life sciences association, but a system that doesn't recognize the value of a \$3,000 diagnostic that could prevent a \$50,000 surgery needs to be changed.

The President's Council of Advisors on Science and Technology, led by Kathleen Behrens, is drafting recommendations for change to make room for personalized medicine. Currently, the field is regulated through the Clinical Laboratory Improvement Amendments of 1988, or CLIA, but the FDA also has shown an interest by issuing draft guidance to regulate the tests. The agency currently will approve kits for sale to third-party labs.

"Certainly more discussion is going to bear fruit," Gardner said.

But with looming concerns over the prediction accuracy of the tests and how they will influence patient treatment decisions, the personalized medicine field faces a lot of work ahead.

Said Abrahams: "I think we're at the beginning of a long journey."

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