view

Personalized medicine & health sciences
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What it means for patient-centered healthcare and how to address its current challenges

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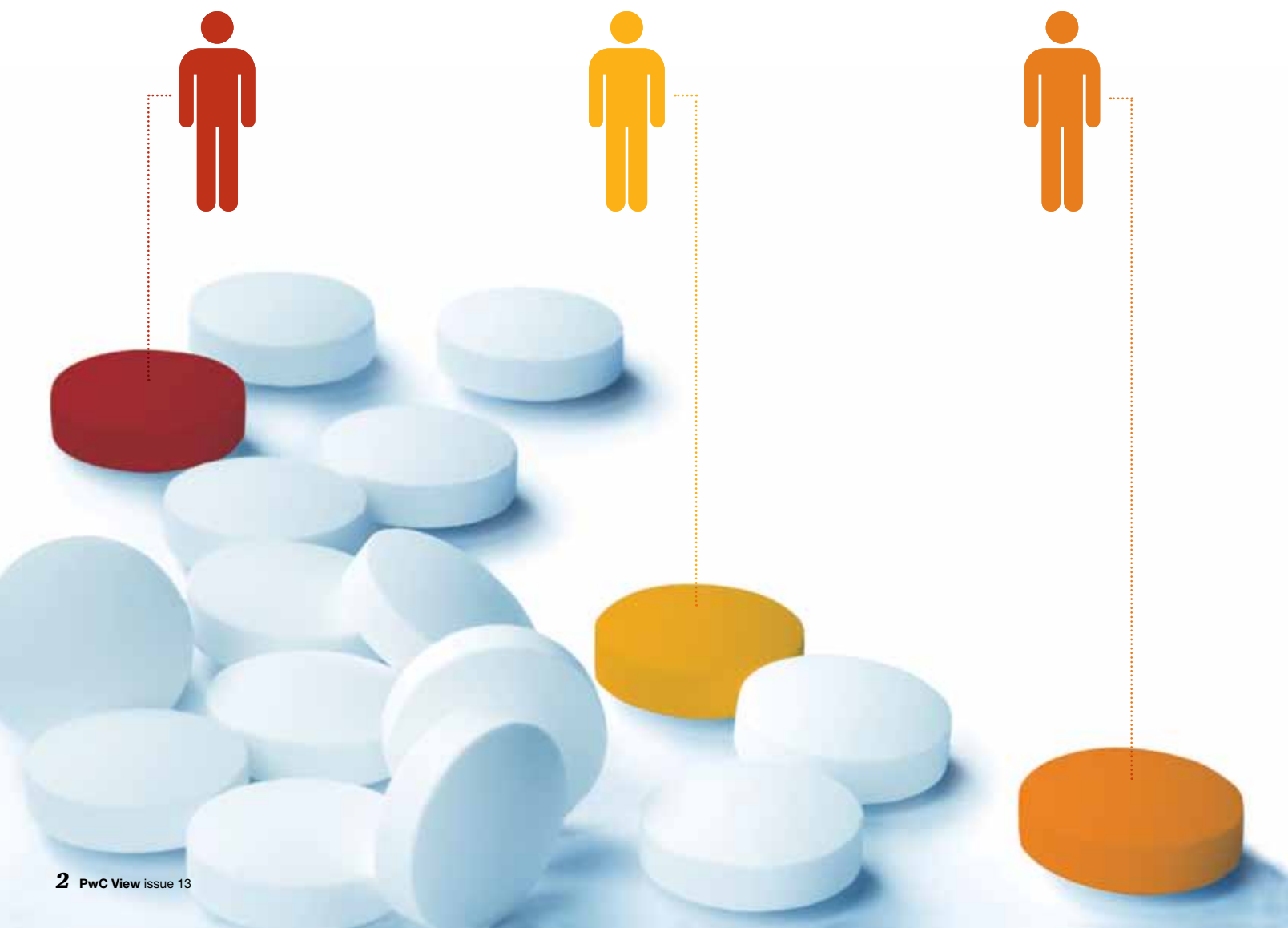

By Gerry McDougall and Matthew Rosamond

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The announcement of the sequencing of the human genome some 10 years ago drove expectations of a rapid advancement in care and the dawning of the age of personalized medicine. While the subsequent decade has seen many false starts and false hopes, the age of personalized medicine now appears to be upon us. There is an ever-increasing number of examples of drugs and diagnostics treatment decisions being guided by a patient's unique circumstances and characteristics, including individual gene and protein configurations. Science fiction? Not anymore. But as providers, practitioners, and patients cautiously embrace the brave new world of customized healthcare through personalized medicine, they are weighing the potential of better treatment and lower costs against a formidable set of challenges.

Personalized medicine—that is, medicine tailored to a patient's genetic and other unique characteristics—is at the core of customized healthcare. This major shift in care will touch everyone: not just patients, providers, and payers but also industries and economic sectors that traditionally have not been associated with healthcare. Personalized medicine will revolutionize the practice of medicine, as clinicians and consumers work together to guide individual behavior and treatment decisions before, during, and after an illness occurs.

Personalized medicine is often described as the right treatment for the right person at the right time. This emerging science has the potential to truly customize healthcare to the patient, enabling providers to match drugs to patients based on their genetic profiles, to identify which health conditions an individual is susceptible to, and to determine how a given patient will respond to a particular therapy. As a result, personalized medicine can eliminate unnecessary treatments, minimize the potential for adverse events, and, ultimately, improve patient outcomes.

But what exactly is personalized medicine? PwC takes a broad view, defining it as consisting of products and services that directly or indirectly leverage the science of genomics (the study of an organism's genes) and proteomics (the study of the proteins that genes create, or express) and that capitalize on the trends toward wellness and consumerism in order to facilitate tailored approaches to prevention and care. As we see it, personalized medicine encompasses everything from high-tech diagnostics to functional foods, to technologies that enable the storage, analysis, and linking of patient and scientific data.[1] For example, personalized medicine may mean either a biologic that targets specific cells or an interactive technology that allows diabetic patients and their physicians to develop customized food plans and exercise regimes.

1 PricewaterhouseCoopers, *The new science of personalized medicine: Translating the promise into practice*, September 2009.

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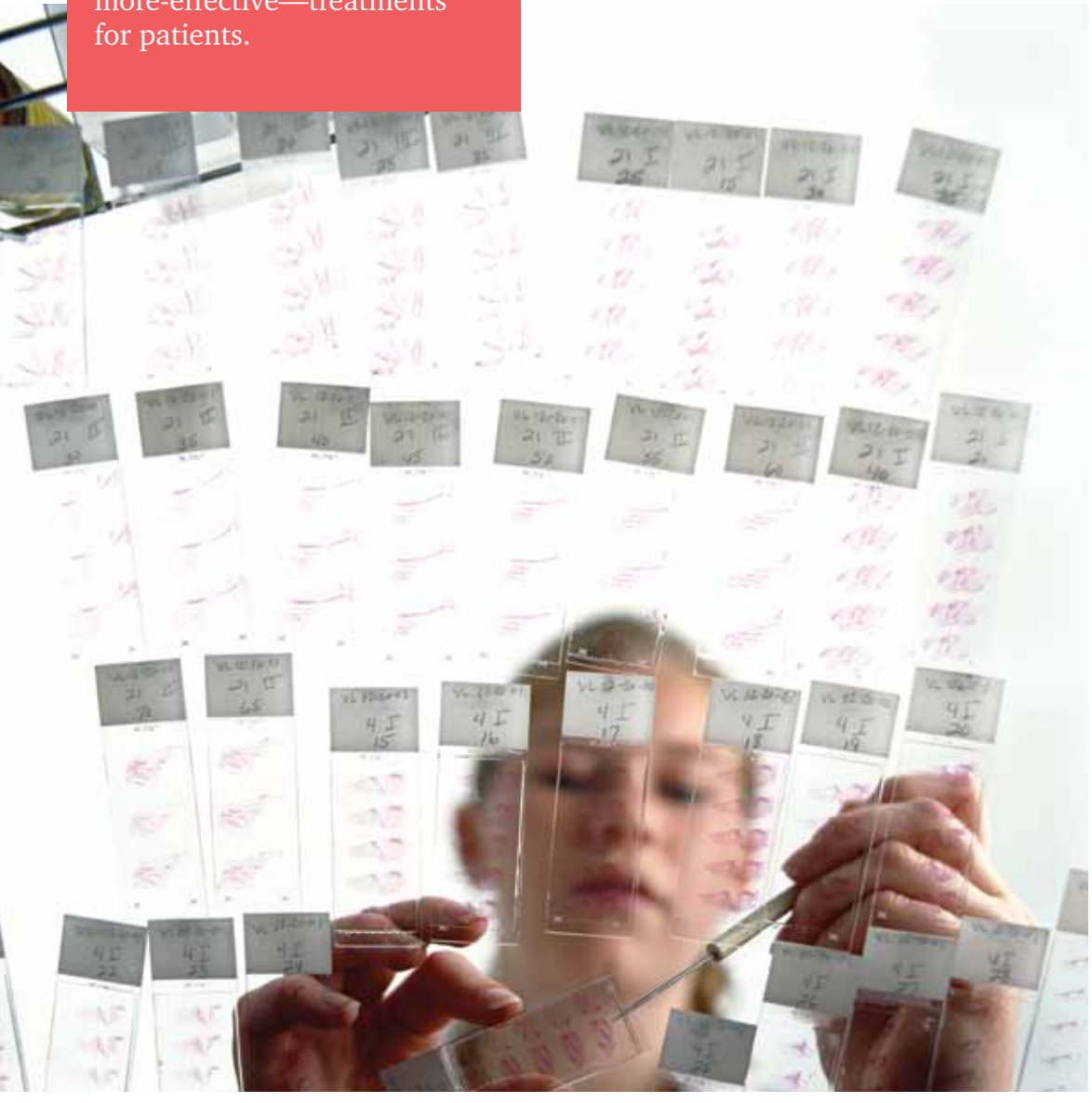

Toward the tipping point

Many in the healthcare industry are wondering whether personalized medicine has reached the tipping point of mainstream medicine and at what point it deserves serious attention from clinicians.

A few health systems are forging ahead and making personalized medicine available to their patients—health systems like El Camino Hospital in Silicon Valley, which last year opened its Genomic Medicine Institute. The institute provides genomic testing covering some 40 conditions and offers genetic counseling services to help patients make informed decisions about treatment. The institute's programs will also provide access to genomics-based clinical trials as they become available.[2]

But outside these pioneers and the largest academic medical centers, most health systems have not yet embraced the practice. However, we see encouraging signs of change:

2 http://www.elcaminohospital.org/Genomic_Medicine_Institute.

From recent conversations we've had with providers both in the US and internationally, we're seeing an excitement and an urgency about how to integrate personalized medicine into a new era of customized care and treatments.[3] As health systems move ahead, it will be essential for medical practice and medical research to work together.

Such collaborations are already occurring in some areas. For example, oncologists and clinical research professionals are experimenting with clinical trial pilot projects to accelerate the process of more quickly applying research findings to patients. Those pilots are guiding doctors in the design of personalized treatment regimens for cancer patients. When health providers partner with scientists and research institutes, they can translate scientific discoveries into more-customized—and more-effective—treatments for patients.

Before such changes can occur, though, clinicians and the organizations where they practice will need to overcome significant challenges in the areas of education, business, and regulation.

The education challenge

One of the fundamental challenges for both providers and patients involves simply keeping up with all the advancements that are occurring. Health providers will have to build expertise in personalized medicine if they want to succeed in the new era of customized healthcare delivery. The rapid growth of research in this field is making it difficult for even the most dedicated clinicians to understand and apply new findings or to interpret diagnostic test results. Ambitious physicians will educate themselves in genomics and proteomics as well as gain knowledge from experts in the field. Health systems will need to recruit physicians and genetic counselors who can interpret the results of sophisticated genetic tests and translate them into effective prevention and treatment strategies. Providers must also communicate to medical colleges the need for more education in the field of genomic and proteomic science.

At the same time, healthcare providers have an important role to play in teaching patients to be co-managers of their own health and wellness. In an era of individualized care, educational efforts that target patients will help raise awareness of and demand for new, personalized therapeutics. The dynamics of the doctor-patient role will change. Physicians will no longer be the sole sources of knowledge, and educated patients will participate more in medical decision making and choice. Providers, for instance, will counsel patients on the benefits of contributing genetic information for research, participating in clinical trials, using health-oriented social networking sites, and donating biospecimens for biobanks.

The business challenge

Health systems also need to better understand how the new approach would change the way they conduct business—from the services they provide to the way healthcare decisions are made and paid for. For example, offering personalized approaches may be a competitive advantage. A cancer center that integrates molecular medicine into patient care might be viewed as a leader in the field, thereby attracting more patients than would other providers that offer only traditional therapies.

In addition, reimbursement decisions may become more complex. When it comes to genetic-based tests or therapies, subjectivity on a case-by-case basis may be required, calling for far greater collaboration among payers, providers, and the makers of drugs, diagnostics, medical devices, and therapeutics. Moreover, healthcare providers must also consider how personalized medicine will affect their technology capabilities and infrastructures. Today, a vast amount of healthcare information is already being collected, including patient histories,

3 PricewaterhouseCoopers and HealthLeaders Media, *The impact of personalized medicine today,* 2010.

diagnostic reports, and clinical research findings. The increasing levels of adoption of electronic health records (EHRs) by hospitals and health systems will ramp up the collection of health data exponentially over the next few years. And this is on top of a growing body of genomic data that ultimately will evolve into billions of data points on every individual, as powerful analytical tools are being developed.

The value of the genomic, proteomic, and other health data being collected becomes greater as it gets shared among research organizations and mined to become more predictive. How well providers manage, share, and make use of that data will be crucial to their ability to provide coordinated care and give broad-based clinical decision support for individualized patient management. As personalized medicine becomes a reality, provider systems, payers, and the pharmaceutical industry will be working together to create a new data architecture that will enable interoperability among information technology systems to facilitate the linking and analysis of health data across the country.

The regulatory challenge

Even though it is outside direct health system influence, the drug development and approval process is, arguably, one of the most formidable barriers to personalized medicine. Once the era arrives when personalized medicine reigns, the current approval process for drug development and commercialization will become outdated. The current structure of the US Food and Drug Administration is poorly equipped to handle all of the many individual variations associated with personalized medicine.

Diagnostics, for example, play a crucial role in advancing personalized medicine because they can help doctors target specific therapies for specific kinds of patients in whom these therapies are known to work. But approval of diagnostic tests and approval of drugs are handled separately, reviewed in two entirely different centers and under very different rules. The regulatory pathway for the commercialization of new diagnostics is unclear due to diversity in approval pathways and the ongoing expectation of regulatory reform.

Many health leaders are talking about developing a common regulatory regime for all healthcare products and services rather than separate regimes for pharmaceuticals, medical devices, diagnostics, and the like.

How employers are responding

When it comes to personalized medicine, employers are beginning to take an active role. First, they're becoming educated about the science and benefits of personalized medicine by consulting with experts and institutions at the forefront of advancement of the new science. Employers are also working with pharmaceutical and diagnostics companies to maintain current, accurate information on the clinical efficacy of personalized-medicine tests and treatments and using the information to inform benefits policies and reimbursement decisions. For example, looking at just one diagnostic tool—Genomic Health's Oncotype DX® breast cancer test—illustrates the potential for cost savings and the ability to spare patients unnecessary treatments. Genomic Health estimates that by identifying those who would not benefit from treatment, the test can reduce chemotherapy use by 20 to 35 percent and yield a savings of approximately $1,900 per patient tested.[4]

At the same time, employers are working with insurers in the analysis of claims data to identify unmet needs that personalized medicine could address. And they're looking at redesigns of reimbursement models to focus on pay for performance.

As more and more companies embrace these practices, the road to full execution of personalized medicine becomes far easier to travel. And from where we sit, that's an inevitability that's bound to occur and will benefit everyone.

4 http://www.oncotypedx.com/Managed-CareOrgs/EconomicValidity.aspx.

Looking ahead:
How personalized medicine could change pediatric cancer treatment

What might personalized medicine really mean for patients? Here's an example that Beth Baber, PhD, a cancer researcher and mother of three, is working on that she intends will soon be a reality. Several years ago, Baber's own 15-month-old son was diagnosed with high-risk neuroblastoma—a malignant tumor that originates from the spine. After seven rounds of intensive chemotherapy, surgery, and retinoic acid therapy, Nicholas remains in remission. However, the experience opened Baber's eyes to the problems inherent in the one-size-fits-all treatment approach that is the current standard of care for childhood cancer.

Baber is changing things through an organization she cofounded, The Nicholas Conor Institute (TNCI). The institute, a not-for-profit 501(c)(3) enterprise, has formed TACTiC™, a collaboration of personalized-medicine diagnostics and therapy research organizations. Operating as the translation and business management hub, TNCI receives its funds from foundations and grants and disseminates the monies to the TACTiC™ partners for research and development of pediatric cancer diagnostic kits and new treatments, all of them focused on stratified populations and personalized cures. Baber's regimented, business-oriented infrastructure maintains careful control over initiatives to carry new discoveries forward to targeted life sciences companies. With TNCI leading the way with venture philanthropy funding, the companies are relieved from early-stage risks and costs. Upon commercialization, license fees are returned to TNCI for sharing with the TACTiC™ partnership and reinvestment into further research.

Diagnosis and treatment in 2010

Today, there is no defined protocol for diagnosing childhood cancer, so pathologists vary in levels of rigor in the testing they undertake. In cases in which they are less aggressive, there's greater likelihood of misdiagnoses. When it comes to treatment, children with rare cancers such as neuroblastoma are all given the same chemotherapy drugs; there is no personalization of treatment approaches. Furthermore, because relatively few children get cancer (childhood cancer accounts for less than 1 percent of all cancer), few therapies are tailored to them. Children often are treated with much higher doses of drugs originally designed for adults. Such drugs are extremely toxic and therefore harsh on young, growing bodies.

The result? Treatment is usually performed through trial and error, leading to unnecessary pain and suffering because the treatment for each form of cancer is so different. Additionally, the majority of children who survive after chemotherapy and/or radiation therapy develop a plethora of long-term side effects, such as infertility, hearing loss, abnormal bone growth, secondary cancers, and a marked decrease in the functionings of the heart, lungs, and kidneys.

Diagnosis and treatment in 2020

In the next decade, The Nicholas Conor Institute hopes to see cancer therapy customization for each and every child. Initially, rather than requiring the costly development of new treatments, TNCI is working with biotechnology firms and other organizations to develop companion diagnostics that will provide better guidance for the use of existing chemotherapy drugs, including those that have been shelved because they were thought to be ineffective. Companion diagnostics could help identify exactly who would benefit from a particular therapy, so that drugs could be pulled off the shelf and commercialized for children.

TNCI is also collaborating with diagnostics maker AltheaDX to develop a uniform approach to making the cancer diagnosis—by way of a single, definitive test that could be performed from a single biopsy. A definitive diagnosis would portend the optimal chance that a child would be immediately placed on the right treatment and therefore have the best chance of being cured.

Already there's promise: AltheaDX is currently producing the first childhood cancer diagnostic panel for small round blue cell tumors—a category of tumors that look much the same under a microscope but that are produced by a variety of cancers, each requiring a different treatment. The diagnostic can differentiate the types of small round blue cell tumors with 99 percent accuracy, so that the appropriate treatment can be prescribed.

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