Competing in an Era of Personalised Medicine

Gerald McDougall of PricewaterhouseCoopers discusses the role of payers and consumers, and how they are paving the way for reforms in the healthcare industry

In the 135 years since Gregor Mendel, whose discovery of inheritance traits in certain plants earned him fame as the figurehead of the new science of genetics, our understanding of the human genome and heritable variation has been a long time coming. Yet, scientific advancement and the pace of innovation have accelerated exponentially in the past decade. Medical scientists now have unprecedented insight into how DNA variations can lead to new ways of diagnosing, treating and, in time, preventing thousands of diseases in all of their sub-classifications.

In 1998, the FDA approved one of the first drugs to leverage the power of genetics to treat disease: Herceptin. It is prescribed only for patients whose genetic tests reveal an over-expression of the protein HER2 due to a gene mutation – an indicator of an aggressive form of cancer that is responsive to treatment by the drug. Unlike chemotherapy drugs, which attack any cell that is replicating rapidly, including healthy cells, Herceptin is customised to target only those cells associated with the disease.

As this example demonstrates, personalised medicine enables physicians to identify an individual's susceptibility to disease, predict how a given patient will respond to a particular drug, eliminate unnecessary treatments, reduce the incidence of adverse reactions to drugs, increase the efficacy of treatments and, ultimately, improve health outcomes.

Today, several factors are accelerating the growth of personalised medicine, moving it beyond concept to enabling tailored approaches to prevention and care. Among them, advances in genomics, proteomics and metabolomics, completion of the human genome map, and development of targeted diagnostics and therapeutics are driving a more personalised approach to healthcare. Expanding storage capabilities and processing power are allowing for sophisticated data collection on individual patients, which, when de-identified and aggregated, can predict public health trends and other benefits. The availability of genetic testing products will be a factor in empowering consumers to participate in managing their own medical risks, putting them at the centre of their own care and engaging them to be active stakeholders in their health and the health system. In the US, the recent passage of health reform, with its focus on reducing redundancy and waste in healthcare, as well as cutting drug costs, will help drive the move toward diagnostic tests based on human genome research. But, personalised medicine is disruptive and its growth will threaten the role of traditional health industry organisations and challenge their business models as new competitors emerge.

NEW MARKET PARTICIPANTS

Already a $232 billion market, PricewaterhouseCoopers projects that the market for personalised medicine will grow by 11 per cent annually to $452 billion by 2015 (see *Footnote*). While the market opportunity for traditional healthcare players is growing, companies outside of the health industry could be formidable competitors because of their skills and experience in targeting consumers, who are contributing to the rapid growth of the wellness market.

The food industry, for example, is poised to capitalise on consumer-focused healthcare. The industry is creating a variety of 'functional foods' – nutrient-rich products aimed at proactive consumers who understand the role of diet in health and wellness, and who want to combat chronic disease through prevention.

Consumer products companies are also leveraging genomics and proteomics to target new products directly to consumers. For instance, one of the world's largest consumer products company's genomics research identified differences in the reaction of older and younger skin at the molecular level. The results led to the launch of a line of skin creams, designed to make older skin 'act' younger via active ingredients that stimulate molecular responses.

Technology companies also are capitalising on the move toward personalised medicine, and new businesses that leverage the web will emerge. Some are providing the computational power to accelerate the process of genome sequencing, while others are exploring other business opportunities, from providing data storage, mining and analysis, to developing the IT infrastructure to support research. As healthcare decisions and treatments are moved to the home, pushed closer to the patient and focused on the consumer, connectivity for services such as home-based monitoring and patient-to-patient social networking will be critical.

As the wellness and technology markets continue to expand and encroach upon traditional healthcare territory, all players in the health industry – from pharmaceutical and diagnostics companies to hospitals and primary care providers to payers – will have to change the way they do business if they are to compete in an era of personalised medicine.

SUCCEEDING IN THE NEW ENVIRONMENT

Personalised medicine represents a distinct set of challenges and opportunities for different market participants: pharma, medical technology (molecular diagnostics), hospitals, physicians and insurers. In order to remain relevant in the new environment, each of these players will need to implement new approaches to reach health-savvy consumers, new ways of thinking, and participate in cross-industry collaboration.

Reinventing the Traditional 'Big Pharma' Model

Pharmaceutical companies will have to discover and develop tailored therapies for smaller markets, rather than placing bets on blockbuster drugs that target broad populations. Many in the pharmaceutical industry view the prospect of smaller markets and shrinking revenues as the greatest challenge that they will face over the next decade as blockbuster drug patents continue to expire. But it is clear that there is the potential for the emergence of 'niche busters' – drugs targeted to small populations but commanding a premium price – to replace some of the income lost as blockbusters go off patent. Educational efforts targeted to consumers could also help to raise awareness of and demand for new personalised therapeutics.

Molecular Diagnostics: An Early Winner

One area of personalised medicine that shows early promise is molecular diagnostics – tests used to identify proteins and other biomarkers of disease, or disease susceptibility. This market segment is expected to grow 14 per cent annually between 2007 and 2012, from $2.6 billion to $5.0 billion (1). Molecular diagnostics come with a high price tag – typically thousands of dollars per test – but many payers will reimburse them if they can help to avoid even higher treatment costs by identifying patients who are more likely to respond to a given drug.

While growth prospects for molecular diagnostics are bright, there is concern in some quarters that rapid growth is outpacing clinicians' ability to interpret test results. The sector also faces challenges related to a potential change in the regulatory process for validating new tests. In addition to regulatory hurdles, diagnostics companies face questions about the evidence required for the reimbursement of diagnostics tests. Pharmaceutical companies and diagnostics companies will need to collaborate with each other and with others across the healthcare continuum to seek greater cooperation on pricing and appropriate reimbursement coverage.

Healthcare Providers in State of Flux

For healthcare providers, personalised medicine offers the potential to improve the quality of care, through more precise diagnostics, better therapies, access to more accurate and up-to-date patient data, and decision support tools. But, in this new environment, allied health professionals such as nurse practitioners and physicians' assistants may play a greater role in care delivery. Physicians could also face competition from pharmacists who, due to specialised training, may be better equipped to help patients navigate the personalised medicine landscape. Thus, providers may have to build new service lines around prevention and wellness in order to replace revenues lost from traditional medical procedures.

Physicians should also become educated in the science and clinical application of genomics and proteomics to interpret the results of sophisticated genetic tests and translate them into effective prevention and treatment strategies. Some physicians might choose to be trained as genomics and proteomics specialists with holistic knowledge of many different diseases and an understanding of gene interactions, eliminating the need for patients to see a variety of specialists to treat their ailments. Others may be trained in engineering as well as medicine to gain a greater understanding of new nanoscale medical devices used for personalised medicine drug delivery and diagnostics. Providers will need to band together to communicate the need for greater education in the field of genomic and proteomic science to medical universities.

In addition, physicians will need to hone their communication skills to provide genetic counselling and address the delicate issues surrounding targeted tests and treatments. The doctor who

is reimbursed for outcomes, not procedures, might have to decline a patient's request for a diagnostic test, knowing the results won't change the patient's prognosis. As the emphasis on wellness grows and health insurance companies (payers) and consumers seek alternative, less expensive forms of care, hospital admissions may shrink, and thus providers may need to deliver new forms of care to maintain their revenue flows. Through better health education of patients, providers can help raise awareness of and demand for new personalised therapeutics and diagnostic tests.

Hospitals should also encourage patients to become educated in personalised medicine and take steps to advance it. The doctor-patient role may well evolve from doctors being the sole source of knowledge to greater emphasis on patient education to support shared decision-making and choice. Providers could, for instance, 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 to accelerate discoveries.

Payers are Leading the Way

How payers approach personalised medicine is critical, as they will have to rethink how they define coverage. Personalised medicine has the potential to reduce payers' costs in the long term by providing the precise diagnostics required to avoid unnecessary or ineffective treatments, prevent adverse events, develop prevention strategies, and deliver more effective, targeted therapeutics. But this potential has yet to be realised, and many payers are concerned that the high costs of new targeted diagnostics and therapeutics could be unsustainable.

Payers also worry that the investments they make could benefit competitors. On average, 25 per cent of individuals change health plans each year, in part because most insurance is employment-based. As a result, one payer might invest in costly diagnostics and early intervention that might reduce or eliminate the need for surgery in the future, but by then the member may have changed plans, and the new insurer will benefit from the earlier investment (2).

Despite such concerns, major payers are beginning to embrace personalised medicine. Some of their plans include genetic counselling. Others have enrolled members in long-term research programmes to identify the role of genes and the environment in health, and some have gone even further with members, asking them to provide DNA samples. Such moves by major players will, in all likelihood, spur efforts by other insurers to make forays into personalised medicine.

COLLABORATION WILL BE A KEY TO SUCCESS

As companies search for sustainable models, one theme has emerged clearly: collaboration will be essential to advancing the progress of personalised medicine. No player or sector with its current portfolio of capabilities can succeed in isolation. As the boundaries between healthcare and wellness products and services blur, organisations should consider participating in a wide variety of collaborations within and across industries and between the public and private sectors.

About the author

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Among such examples, providers and health systems can look to other industries, such as consumer products companies, to learn how to market directly to patients and deliver excellent customer service. Payers could team with pharmaceutical and diagnostics companies to maintain current, accurate information on the clinical efficacy of personalised medicine tests and treatments and use the information to inform benefit policies and coverage decisions. And governments worldwide can collaborate with pharma and diagnostics companies to ensure that the appropriate regulatory, privacy and intellectual property framework is in place to support the development and commercialisation of new products.

The move towards personalised medicine is inevitable, but the transition will not be easy. How the healthcare industry responds will be critical in determining its future course and opportunities. Successful organisations will keep their eyes on the prize: the consumers.

References

1. *Diagnostics 2009: Moving Towards Personalised Medicine, PricewaterhouseCoopers LLP*, http://www.pwc.com/us/en/healthcare/publications/diagnostics-2009-moving-towards-personalised-medicine.jhtml
2. Ibid, as referenced in the PricewaterhouseCoopers report, *The New Science of Personalised Medicine: Translating the Promise into Practice*

Footnote

This PricewaterhouseCoopers analysis is based on information aggregated from Kalorama Information, Datamonitor, Frost & Sullivan, Roche, Roth Capital Partners, Natural Marketing Institute, Nutrition Business Journal, Packaged Facts, National Health Statistics Report, Mintel, Feedback Research Services, International Spa Association, IDC, Deloitte, American Telemedicine Association, Visiongain and RNCOS. Ranges or mid-points were used for those markets where estimates have varied particularly widely.