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Personalized healthcare 2010

Are you ready for information-based medicine?

deeper

Executive brief

Introduction

The healthcare and pharmaceutical industries have been buzzing with the promise of personalized healthcare since the inception of the human genome project. As this decade unfolds, information technology will accelerate the delivery of advances in medical science and technology to the public. How will the convergence of information technology and life sciences impact the future? What capabilities will stakeholders need to participate in an increasingly networked industry where information is paramount to progress? How will stakeholders choose the technologies to implement?

A decade of change

During the past decade, life sciences and information technology began to converge, resulting in significant and life-impacting research – the result with perhaps the highest impact to date being the sequencing of the human genome and its influence on how clinical researchers now investigate methods and molecules that could improve the human condition. Knowledge gained through human genome sequencing is driving recent achievements in genomic, proteomic, molecular biology and bioinformatics. As this decade progresses, next generation medical science technology and capabilities, enabled by increasingly "smarter" information technology, will change the discovery, development and delivery of new treatments even more dramatically. For example, biopharmaceutical research will continue to shift from a small, molecule-centered approach to one of stronger biomedical emphasis. This shift will focus on moving from the molecular actions of small molecule compounds toward delivering biologic-based diagnostics and therapeutics. Thus, healthcare will become increasingly personalized as these biologic-based diagnostics and treatments become standard practice.

Significant changes in information technology have occurred over the past decade. Recent information technology advances have significantly reduced the cost of storage, enabling the possibility of access to hundreds of biological databases produced by research groups around the world. Storage technology discoveries, high-performance computing technologies and advances in digitization technologies have given rise to the digitization of patient clinical data (i.e., electronic medical records) and made digital medical imaging increasingly common. Semiconductor technologies have been used to help create microarrays for more complex and efficient gene expression. These scientific advances, combined with new progress in information technology, are giving "new life" to researchers, physicians and patients in medicine and life sciences, forever changing the methods used for preventive, diagnostic and therapeutic activities. The aggregate result of the combination of these advances in medical science and information technology, along with rising consumerism, have the potential to create significant medical breakthroughs benefiting the human condition.

A decade of progress

A future where genetic profiling or patient stratification based upon genetic variance is routine is not that difficult to imagine. Diagnosis based on genotypic and integrated phenotypic data (i.e., clinical genomics) will result in more effective treatments earlier, extending the life of the population and improving the quality of life. Readily available, integrated patient data will help to identify patients at risk for adverse drug reactions, improve clinical trials and drug discovery and tailor individualized treatment for a variety of diseases. But, we have barely begun to see the impact that information technology will have on life science research and healthcare delivery.

The application of information technology advances to those discoveries in science and medicine is giving rise to a new discipline, information-based medicine, which provides new knowledge by integrating and analyzing data coming from patients' clinical information, medical images, the environment, genetic profiles, as well as molecular and genomic research efforts. Information-based medicine is the marriage of information technology with the practice of medicine and pharmaceutical research, for improved disease diagnosis, therapeutics and healthcare delivery. Simply, information-based medicine is the use of information technology to achieve personalized healthcare.

How will healthcare industry stakeholders not only prepare for this rising tide of data, but also increase the benefits of information-based medicine throughout the value chain – from drug discovery to healthcare delivery? As the very nature of medicine changes, what key capabilities will companies need to develop so that they can benefit from the environment of reduced waste and risk that revolutionary new information and scientific technologies will afford? Benefits accrued from information-based medicine will vary depending upon the stakeholder: the patient, the provider and the payer. And, thus, the resultant changes will vary across the entire healthcare landscape.

Societal changes, along with disruptive technologies in medicine and information technology, will impact pharmaceutical and healthcare institutions, thus creating new business models and methods in healthcare and impacting every person's day-to-day life. It is anticipated that these disruptive technologies will enable the following predicted changes by 2010:

1. Medical science breakthroughs will become increasingly common, due to increasing consumerism.
2. Genetic testing will be routine for some population groups, and associated privacy and discrimination policies will be determined through a broad debate involving government, industry and citizens.
3. Several major diseases will be understood at the molecular level, including relevant proteins and pathways, with clearly understood disease mechanisms.
4. Some subpopulations at risk for adverse drug events will be identified for many therapeutics, resulting in increased drug discovery productivity and targeted clinical trials.
5. Healthcare will become wellness care, making pre-symptomatic diagnostics and treatments commonplace.

How will these predictions become reality? Three underlying commonalities will help bring these predictions to fruition: patient care, policy implications and progress in scientific and technological advances.

Compelling drivers for change: Patients, policy and progress

Patient care and rising consumerism

The changing demographics of our society are well known. The fastest growing segment of the American population is over 65 and within that segment, the most rapidly growing group is over 86.[1] By 2050, a quarter of all Americans will be older than 65, an increase of 14 percent from 1995, and people older than 65 utilize three to five times more healthcare services than their younger counterparts. Europe and Asia are experiencing this same demographic change.[2]

Not only are more people receiving healthcare, but also estimates, which vary by disease area, suggest that therapeutics appear to be effective for only 20 to 60 percent of patients prescribed.[3] And, nearly 200,000 people die from adverse drug reactions and misdiagnoses each year.[4] Age, body weight, race and gender are all known causes of variation in therapeutic response. In the future, it may be considered unethical to expose patients to the risk of adverse events without performing fast, simple DNA tests. Merged advances in scientific and information technologies can improve patient outcomes since identification of responders versus non-responders helps avoid adverse reactions and improve patient quality of care.

As more and more prospective patients enter the market, pressures from consumers, employers, healthcare providers, payers and regulators will increase and drive the shift toward data integration and knowledge management in the development of diagnostics and therapeutics. Medical science breakthroughs driven by consumerism will be influenced by these trends. The authors of "Thinking About the Future" voiced this prediction in 2001, "The combination of demographic shifts and cost pressures and a flood of new technologies – both biological and digital – promise that the new century and the coming generation will see the creative destruction and rebirth of what we know today as health care."[5]

Not all consumers are pressing for medical advances. While the benefits to be realized by genomics are enormous, there is concern over the acceptance of genomics-based medicine by both consumers and healthcare providers. Consumers are concerned about their right to privacy or fear of discrimination based on their personal and genotypic data. In a Gallup News Service-sponsored survey, 76 percent of those surveyed opposed giving genotypic information to health insurers and employers.[6] Some physicians are also unprepared to think in terms of genomics-based or personalized medicine. Gaining consumers' trust in genomics-based medicine may be difficult. This concern will fuel debate that will ultimately result in health policies about responsible use of this information. However, successful diagnosis and treatments, such as those seen in today's HER-2 treatment for breast cancer, should increase consumer acceptance of these changes in medicine.

Health policy and global spending

Advances in medical science and medical technology will have limited impact if health policy issues are not simultaneously addressed. Privacy, security, bioethics and bio-discrimination are some of the policy issues to be solved by world governments. At the local level, creation of healthcare policies within an institution can have a huge public benefit, as in the case of infectious diseases, such as SARS. Healthcare community efforts that connect stakeholders are becoming more affordable and being adopted by leading hospitals. There is a trend in the healthcare standard communities to give the patient ownership of his or her medical data and thus move the control of the information from the institute to the patient. This trend may lead to the need for "BioBanks," which will be trusted entities that mediate among healthcare organizations, patients and research institutes. Consumers, healthcare providers and health policy workers must have access to realtime, reliable and safeguarded information. Implementation of world, state and local policies will have global benefits for clinical research, infectious disease research and containment and terrorism measures, as well as financial results and quality of care.

One indicator of health policy can be viewed through spending. Global health and administrative policies and associated budgets are encouraging molecular epidemiology and research leading to the development of personalized healthcare. Some examples include major initiatives in the United States, the United Kingdom, Singapore and Japan.

Information-based medicine's focus on the molecular level of disease is aligned with the United States National Health Institute's "Roadmap Initiative for Medical Research."[7] Its themes are:

- New Pathways to Discovery
- Research Teams of the Future
- Re-engineering the Clinical Research Enterprise.

New Pathways to Discovery focus areas range from molecular imaging and the study of personalized profiles of cell and tissue function at an individual level (leading to better diagnosis and treatment) to studies of biological pathways and networks. This work will help accelerate the achievement of the 2010 predictions of routine genetic testing, personalized medicine and improved quality of patient care.

Another United States project relevant to personalized healthcare and information-based medicine was initiated in July of 2003. The National Cancer Institute (NCI) announced its intention to create a cancer-based biomedical informatics network, called the Cancer Biomedical Informatics Grid (caBIG). The goal of this effort is to build a biomedical informatics network that will connect cancer research-related elements of data, tools, individuals and organizations and leverage their strengths and expertise globally. caBIG will help redefine how research is conducted, care is provided and patients and participants interact with the biomedical research enterprise.[8] Participation in this kind of network – based on universal standards for information security and ethical use – means that all stakeholders must adhere to strict security measures for accessing, utilizing and transmitting patient data.

The Singapore government sponsors disease-specific work with more than US$1 billion in initiatives, including a National Tissue Repository to accelerate genomic research and formation of disease-specific institutes.[9] The Kobe, Japan government is sponsoring the Kobe Translational Research Center to link genotypic and polymorphism data from confined target population in the Kansai region to pathophysiological data and patient outcome data.[10] The United Kingdom has allocated US$3 billion for the creation of a National Health Initiative (NHIS) that is establishing a national digital health infrastructure.[11] The UK Medical Research Council is sponsoring the academic consortium led by Oxford and Cambridge Universities for the National Translational Cancer Research Network (NTRAC).[12] Other initiatives are occurring around the globe. Initiatives such as these, and their aggregate results, will help accelerate the development of genomics-based diagnostics and therapeutics on a global basis.

Progress in science and technology

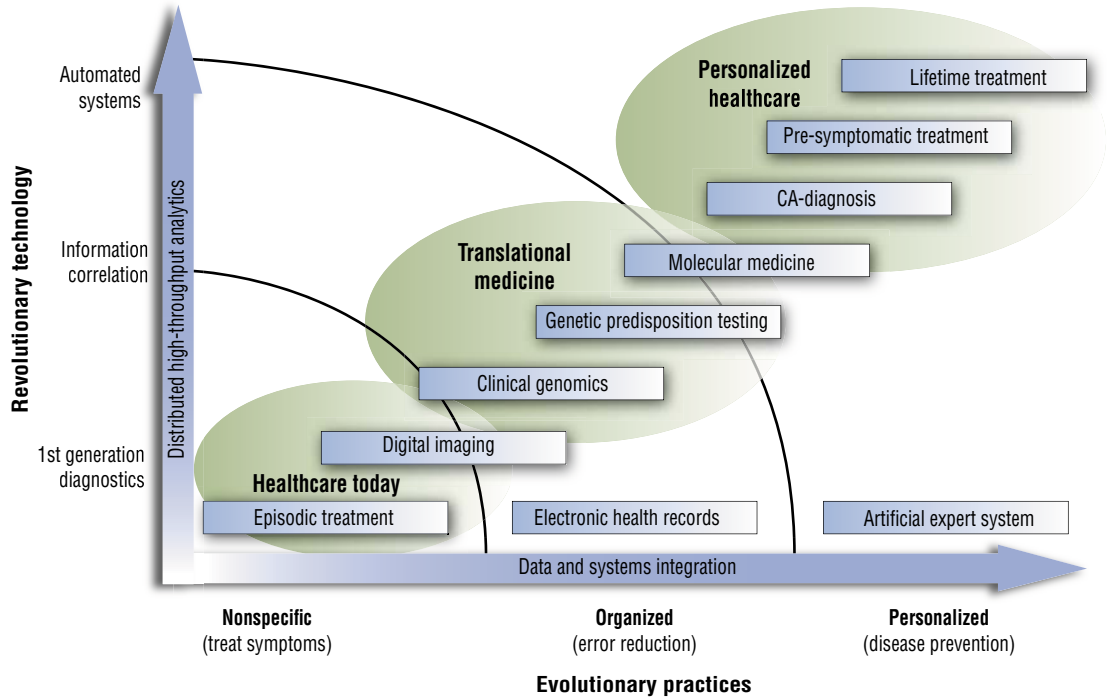
Personalized healthcare will be achieved through a composite of scientific advances and new technology, and creative uses of information technology and human thought in the practice of medicine. Scientific advances and discoveries, as well as new technological capabilities, will be revolutionary. Innovation in the practice of medicine will be evolutionary. The combination of revolutionary technologies and evolutionary practices form information-based medicine and will shape the future of personalized healthcare (see Figure 1).

Informed prevention in public health

Countries in Asia are working to develop disease surveillance systems that will collect various forms of data from multiple hospitals, clinics and other agencies. The goal is to enable countries to respond quickly to disease outbreaks such as SARS and bioterrorism attacks. This system has the potential to be expanded to collect other forms of clinical data, including individuals' genomic information. The data could be analyzed and correlated for several purposes: the identification and validation of susceptibility genes related to certain diseases, the identification and validation of novel therapeutic targets, greater focus in clinical trials and the development of molecular-based medical diagnostics.

The system could also help improve the validity and reduce bias for assessment of environmental exposure, allow for evaluation of subclinical or early disease markers and decrease the heterogeneity in the classification of diseases in descriptive studies. Additionally, it could improve precision in analytical epidemiology – understanding the contribution of genetic and environmental factors and their interaction, so that the risk of developing disease can be more accurately determined.[13]

Figure 1: Market trends and drivers: revolutionary technologies and evolutionary practices.



Source: IBM Life Sciences Solutions

An example of the convergence of revolutionary technologies and evolutionary practices can be seen in pharmacogenomics, the study of how an individual's genetic inheritance affects the body's response to drugs. Pharmacogenetics, the coexistence of genetic polymorphisms in drug metabolizing enzymes, targets, receptors and transporters, in the context of drug and non-drug influences, may result in high frequencies of unusual drug reaction phenotypes.[14] Therefore, drugs targeted to genotypic profiles would have greater safety and efficacy, preventing some of the 200,000 deaths a year from adverse drug reactions and missed diagnosis.[15] Genomic research will be able to identify the possible presence of disease even before birth.[16] At the same time, the tendency of medical professionals to treat symptoms will evolve to an approach of personalized disease prevention based on pre-symptomatic treatments, therapeutics and life-style changes. Treatment will shift from episodic encounters to the management of disease with information and prognostic technologies. This process has already started, and will be greatly aided in the future as information becomes more integrated – allowing observations and test results to be correlated to find previously unidentified patterns associated with disease. Selected revolutionary technologies and evolutionary practices are discussed in Figure 2.

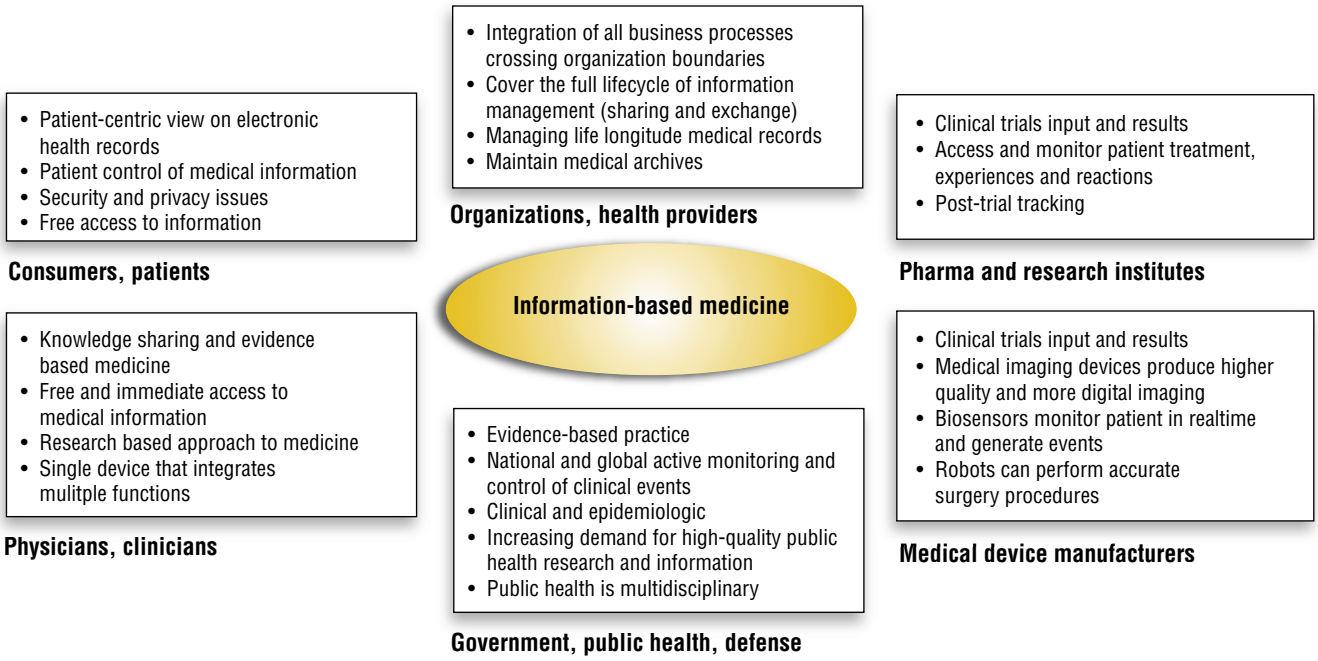
The revolutionary and evolutionary forces inherent in the shift toward information-based medicine will play off of one another, compounding as information and scientific technologies advance, and more individualized patient information is captured and shared across the healthcare value chain (see Figure 3). The result will be increasingly individualized healthcare based upon a molecular understanding of disease with associated genomics and genetics based therapeutics.

Figure 2: Selected revolutionary technologies and evolutionary practices.

Revolutionary technologies	Evolutionary practices
• Advanced imaging technologies combined with high-performance computing result in highly accurate devices that can look inside the body, travel in the body and construct 3D images in realtime • Molecular imaging to determine metabolic activity of disease, patient stratification, near-immediate observation of drug efficacy, matching drug to patient and patient to drug and superior capability for diagnosis and disease-state tracking • Systems biology that combines molecular-based knowledge of diseases with an understanding of how genes work to form networks; Disease reclassification based upon an understanding of genomics and systems biology that drives the next generation of drug discovery • Next-generation in vivo diagnostics: molecular imaging with "smart" contrast enhancement agents, molecular scale implantable sensors for short- or long-term use (such as for gene therapy), transitional passage through body, microarray-based "chips".	• Transparent access to and integration of heterogeneous data from diverse sources (patient records, lab test results, demographic data, life-style data, pharmaceutical information, genotypic and phenotypic data, genealogical data, pathological, epidemiological data) • Integration of genomic, proteomics, metabolic data in the clinical domain, with tools and applications from various sources that are plug-and-play • Knowledge sharing and online collaboration in a multidisciplinary environment • Disease mining, population studies and targeted treatments • Changing perceptions of healthcare as wellness care, not symptomatic care • Increased use of electronic medical records linking a patient's clinical data with environmental, demographic, genealogical and genomic data to form foundations for personalized healthcare • Information systems linking departments within a hospital enterprise, as well as linking partners within the ecosystem to form an electronic infrastructure.

Source: IBM Life Sciences Solutions.

Figure 3: Information-based medicine ecosystem.



Source: IBM Life Sciences Solutions

The future of healthcare is here: Are you ready?

To quote the futurist William Gibson, "The future is not so hard to predict. It's already here. It's just not equally distributed."[17] Many industry leaders in pharma, academic and medical research centers and hospitals have already taken the first steps toward information-based medicine. By 2010, information-based medicine will change not only the information technology capabilities of these businesses, but their ability to organize, share and utilize knowledge and information across the enterprise and the value chain. Will you be ready? The following is a glimpse into the future of personalized healthcare through scenarios in development today.

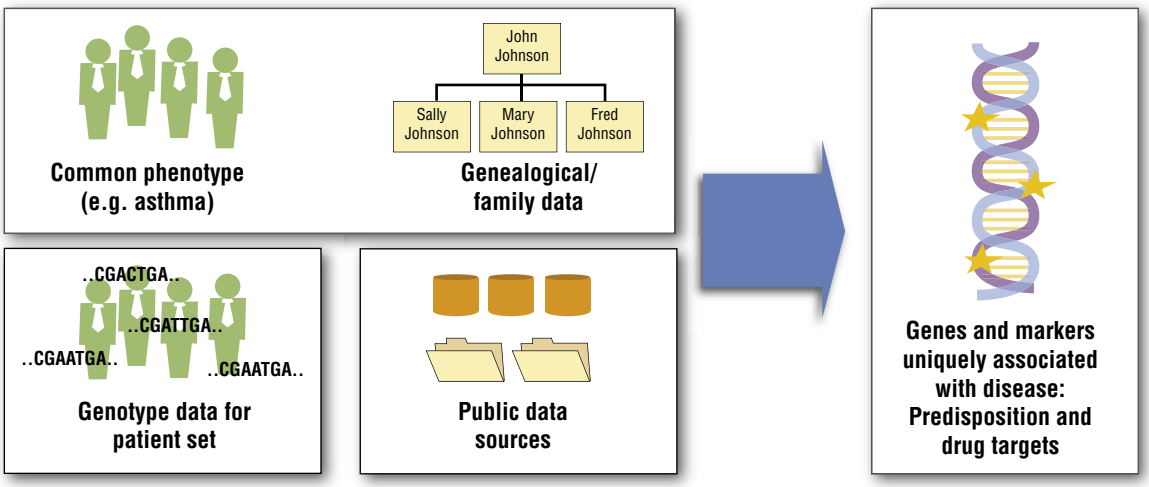
Patient quality of care: Targeted treatment solutions[18]

The first step toward patient oriented quality of care is the development of an infrastructure to support data integration, including information such as electronic patient records, laboratory data, diagnostic imaging, tissue samples and genealogical records – and the algorithms and tools required for analysis. The development of large-scale electronic record keeping systems for the purpose of practicing medicine, including presymptomatic testing and diagnosis, is a critical element in the evolution of healthcare.

These electronic records will be sophisticated heterogeneous objects containing molecular (genotypic) as well as clinical (phenotypic) data. Some electronic medical records have been implemented already, but are primarily for the purposes of administrative and clinical information management (e.g., billing and treatment history) and do not yet have the integrated capabilities required for other uses, such as electronic information management systems at the point of care (e.g., identifying subjects for clinical trials or collecting and analyzing data on side effects). However, the existence of these infrastructures for large-scale electronic record keeping and the continued development toward better, more sophisticated systems confirms the fact that personalized healthcare is beginning to gain momentum.

As phenotypic and genotypic patient data repositories become commonplace, solutions that link these data in diverse systems will become more common too. Integrating these data will help researchers identify and validate novel targets, conduct more focused clinical research and revolutionize the way diseases are diagnosed and treated (see Figure 4). The integration of genotypic and phenotypic data is called clinical genomics. The analysis of these integrated data can lead to the discovery of genes and markers uniquely associated with disease, as well as the predisposition for disease and the discovery of specific drug targets.

Figure 4: Clinical genomics: Integration of phenotypic and genotypic data.



Source: IBM Life Sciences Solutions

Targeted treatment solutions

An information-based medicine implementation project at the Mayo clinic includes the creation of a data warehouse that contains clinical and genomic data. A Web-enabled user interface allows authorized clinicians and researchers to access unprecedented amounts of patient information including demographic, diagnostic, physiological and genomic data in a security-rich environment. For the first time, doctors are able to electronically query massive amounts of patient data to gain insight into disease prevention, diagnosis and treatment. Mayo physicians can perform queries on more than 4.4 million patient records, enabling the identification of candidates for participation in clinical studies in minutes, instead of months. IBM and Mayo researchers are developing smarter software to find patterns in large groups of genes that signify whether a group of patients with common symptoms have a certain variation of a disease. The system will first be used for clinical research, but ultimately for improved patient care, leading to personalized healthcare.[19]

Transparent access to multidimensional heterogeneous data and interoperability of various software applications from multiple sources across drug discovery, development and delivery processes are key capabilities to break current data and communication flow barriers and increase collaboration across the information-based medicine value chain. Integration of electronic patient records, imaging, phenotypic and genotypic data is a first step. However, the study of one individual's data is of limited value to clinical researchers. It is the study of these data in correlation with large populations' data that is of greater value.

Advances in medical science and medical technology

Scientists found that genetic susceptibility may explain why severe acute respiratory syndrome (SARS) raged in Southeast Asia and nowhere else in the world besides Toronto. Researchers found a certain variant in an immune system gene called human leukocyte antigen, or HLA, made patients in Taiwan much more likely to develop life-threatening symptoms of SARS. The gene variant is common in people of southern Chinese descent. The researchers found that Taiwanese patients with severe cases of SARS were likely to have a version of the HLA gene called HLA-B 4601. No indigenous Taiwanese ever developed SARS because they do not have the variant of the immune system gene. HLA-B is also seldom seen in European populations.[20]

Large-scale population studies are a key tool in the research leading to more individualized treatment solutions. deCODE genetics, a drug discovery and design company headquartered in Reykjavik, Iceland, utilizes population genetics and large-scale population studies in both Iceland and the United States to help isolate the genetic causes of 50 common diseases, including osteoporosis, stroke, hypertension, heart disease, obesity, Schizophrenia and Alzheimer's. These diseases result from the interplay of multiple genes and environmental and health factors within a very complex pathological chain.[21]

Unraveling this complexity requires the ability to gather and correlate detailed information on disease and genetic variations across the entire population of Iceland and correlate these data with the more heterogeneous population of the United States. deCODE combines genetic, disease and genealogical data to determine the genetic causes of disease. deCODE scientists have uncovered the association of a gene likely to cause stroke and myocardial infarction with a gene that may be associated with obesity. deCODE has developed a statistical analysis tool called Clinical Genome Miner – Discovery (CGM-D) to do their basic analysis.[22]

Medical technology advances to understand the cause of disease

Researchers at the University of British Columbia Research Centre, iCAPTURE, are studying genetic susceptibility to environmental factors, particularly for the heart, lung and blood vessels. They have created a system to understand how expressed genes can change the structure and function of cells, tissues and organs within the body to cause disease. iCapture integrated disparate data sources to perform complex queries that are leading to a deeper understanding of disease mechanisms and laying the foundation for information-based medicine.[23]

Within the next decade, molecular diagnostic products will likely enable researchers to predict a patient's response to therapy based on the genetic makeup of a tumor (in the case of cancer), the viral genotype (for viral infections) or the genetic make-up of the patient (for a wide variety of conditions). HIV genotyping is an early example of how treatment decisions are made based on the genotype of the virus. Another example of current advances in molecular diagnostics is Roche's myocardial infarction diagnostic developed with deCODE genetics and Affymetrix.[24] The FDA's recent decision[25] on the acceptance of pharmacogenomics data in support of new drug approvals demonstrates that the requirement for management of information will become standard for both diagnostics and therapeutics.

Molecular medicine will be instrumental in determining metabolic activity of disease, patient stratification, near-immediate observation of drug efficacy, matching drug to patient and patient to drug and superior capability for diagnosis and disease-state tracking. However, without the requisite information technology to aggregate and integrate the data these new advances generate, progress made toward personalized medicine will be limited.

Medical technology advances

Researchers at the University of California at San Francisco (UCSF) are collaborating on an initiative expected to speed the pace of medical research and help patients by providing more accurate diagnosis. The project will start with Alzheimer's disease and other neurological illnesses and will link doctors, clinicians and researchers across the UCSF system. One of major challenges will be differential diagnosis of patients with neurodegenerative disease. Because patients enter the center at different stages, it is important to track changes of brain images. The center has "many hundreds" of magnetic resonance images (MRIs) of patients' brains. Keeping the images in a database allows for data mining and easier comparison of changes. The study will compare data from other patient images, as well as track individual progression.

"UCSF will add cancer research, specifically related to breast cancer, to the collaboration," said Regis Kelly, UCSF executive vice chancellor, whose academic background is in molecular biology, a discipline that has made strides in breaking down barriers to work with other scientists on the Human Genome Project and related work. From a personal perspective, Kelly said, "I'd love to help capitalize on the movement to create higher-quality molecular databases."[26]

Information-based medicine reflects the scientific advances that have taken place over the past 20 years in medical devices, medical imaging, therapy development and information technology. It also mirrors the changes that have taken place in healthcare, the cooperation between multidisciplinary processes (e.g., pharmaceutical, devices, genomic) in the medical domain and the growing impact of information technology on healthcare. These changes lead the way to future discoveries.

Challenges, concerns and collaboration

While there are many exciting scientific and medical technologies that promise a new world of medicine, there are some significant challenges to their implementation. The healthcare enterprise is the common denominator in the personalized medicine equation. Unfortunately, devices within the healthcare system do not function as a system today. This creates a number of limitations, including the inability to easily fuse data, share resources, upgrade algorithms and systematically collect data for further analysis. Medicine has not always moved ahead as quickly as technology. Some amount of inertia is useful to provide a necessary level of safety. However, the key issues for the lag-behind include the validation and certification of equipment changes and upgrades, the cost associated with replacing outmoded equipment and the difficulty of intermixing hardware and software from different vendors and generations.

The healthcare infrastructure is very fragmented and struggles as a low-margin business with increasing costs. Managed care generally treats any new business model with suspicion if it does not provide immediate relief from those costs.[27] A comment from the Executive Forum on Personalized Medicine expressed this sentiment about change, "We healthcare administrators are a conservative bunch. But, if we took this job because we don't like change, now is the time to quit."[28] History has shown that change in the healthcare system is not rapid.

Compliance with the Health Insurance Portability and Accountability Act (HIPAA) and the implementation of other privacy and data standards to protect clinical and genomic data are critical elements of progress. Most institutions are unprepared for the enforcement of HIPAA with the combined complexity of managing patients' privacy and the data necessary for clinical research. The ripple effect of a lack of security and privacy standards across the enterprise – and industry – could be significant. Security and privacy issues, particularly the management of diagnostic data and the interfaces to clinical and hospital interfaces, can significantly impact the IT budgets of hospitals, clinical researchers and payers.

The common thread throughout the information-based medicine ecosystem is the need for knowledge derived from standardized data that can be shared across corporate, agency, physician, provider and consumer boundaries and provided in a safeguarded, compliant manner based upon policies that define the rights and responsibilities for the data being accessed. HIPAA and other regulations limit the information that can be shared across and among institutions, placing researchers in a challenging position as they balance obtaining requisite data with patient rights. Information systems for managing de-identified patient data through universal global identifiers will be critical to addressing this issue.

Next steps

The human genome announcement in 2000 sparked explosive growth in genomics, proteomics and other biosciences and created a new need for information technology to unlock knowledge and value from new scientific discoveries. Much of the focus in seeking value from the new science has been on drug discovery within the pharmaceutical and biotech industries, and the first fruits of this work are just beginning to appear in the pharmaceutical pipeline. Yet, the next phase of value creation has already begun. Applying techniques of high-throughput biology and genomics to large patient populations and using powerful computing to analyze, model and simulate is the next wave of the new biology, one that we call information-based medicine. What does your company need to do to function in such a world? The following questions are designed to help industry stakeholders assess their preparedness for participation in information-based medicine.

- *How integrated is your information infrastructure?*

  Can your institution's genomic data be integrated with your electronic and patient records, clinical and imaging data? Can key data storage, data processing and diverse data sources be accessed by the hospital, medical research center or bio-pharmaceutical industries?

- *To what extent are you ready to work collaboratively across drug discovery, diagnosis, treatment and delivery?*

  Can your institution share data required for clinical trials or collaborative research with others on your team, whether they are part of your organization or are extended team members? What processes and platforms are in place to enable realtime data sharing and collaboration across a diverse value chain of stakeholders who will need and use integrated data for a variety of purposes?

- *How secure is your information?*

  How does your team share HIPAA-regulated data with others on your research teams? Are your data transmissions secure enough? How are you controlling access and distribution of the contents of your tissue banks? What measures has your company taken to increase the security of information, protect patient privacy and help ensure the ethical use of data and information as it is accessed, used and transmitted over both public and private networks? Is your information technology infrastructure protected from threat?

- *HIPAA: are you ready for April 15, 2005?*

  Compliance with HIPAA regulations will be enforced on April 15, 2005. Do your systems provide security features and protect patient privacy while still allowing your researchers access to requisite data, both within your institution and among your collaborative partners?

- *How much will you invest in the future? How will you plan for it? How will it affect your competitive edge?*

  Is your company prepared to make investments in information technology, computing, modeling and simulation capabilities, and text and data mining? Do you plan to, or have you begun to, invest in improving productivity tools to facilitate data collection and access at the delivery level?

- *Do you have the right alliances and partnerships to share your implementation burdens? Do your partnerships include key technology providers and enabling partners?*

  Do current and prospective strategic partners have acumen for efficient data flow across development, continuous submission, marketing and delivery? Do their systems hinder or enable the realtime flow of integrated information? Does your information technology provider understand the unique requirements of healthcare? Do you need help integrating numerous technologies across the enterprise?

- *Are your data and business goals aligned?*

  Is your patient information available when you need it, where you need it?

- *To what extent does your organization operate on demand?*

  Is there integrated and seamless access to all patient information across and among enterprises? Are your information processes and procedures open to effectively operate in a multivendor, multi-partner environment? Are your information and other resources organized so that they are available as a single pool regardless of location or use? To what extent do your information systems operate with limited monitoring and systems intervention?

Conclusion

As you observe the implications of evolving patient care, policy and progress in scientific and medical technologies, consider the 2010 predictions for information-based medicine: commonplace medical science breakthroughs, routine genetic testing with requisite privacy and discrimination policies, identification of major diseases at the molecular level with appropriate diagnosis and therapeutics, better safety and efficacy for therapeutics and healthcare that has become wellness care. Will these predictions become a reality?

The scientific and information technologies required to achieve these predictions are available and being applied toward these goals. We stand at the threshold of a decade of great change in the pharmaceutical and healthcare industries, but it will also be a decade of difficult decisions for industry stakeholders – as well as one of uncertainty for the world at large. Breathtaking advances in medical science and medical technology have been made in the last few years. Mankind succeeded in decoding the human genome, learned the programming code for major diseases and developed miraculous drug treatments.

But as the world gets smaller (and more volatile), greater numbers of the population will become more vulnerable to pandemic and bioterrorism threats, such as AIDS, SARS and Anthrax. As genotypic and phenotypic information become more and more prolific, stakeholders across drug discovery, development and delivery will struggle to put volumes of data to work for both themselves and an increasingly demanding patient population. Add to these issues the necessity for keeping genotypic and other patient information private and protected, and industry players face formidable challenges to extracting real value from even the most leading-edge medical advances.

But, as Albert Einstein once said, "In the middle of difficulty lies great opportunity."[29] By marrying advances in medical science and technology – and the data they yield – with information technology, the healthcare and pharmaceutical industries will have more opportunities than ever to contribute to a healthier, safer world. To learn ways in which we might help your company create knowledge from data and move toward information-based medicine, please visit our Web site:

ibm.com/bcs/lifesciences

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