

A NEW ERA OF Diagnostics

Institute for the Future
Health Horizons Program
December 2003
SR-821 B



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ABOUT THE HEALTH HORIZONS PROGRAM

The Health Horizons Program identifies and evaluates trends and discontinuities in the broad health industry landscape and then forecasts what these mean for health care and health-oriented companies over the next 3 to 10 years. We combine a deep understanding of the health care delivery system, consumer behavior, health technologies, and societal forces to identify where to play and how to win in the emerging health economy. Specifically, our research identifies sources of value that will shape the products and services consumers will seek to support their health in the future.

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Introduction



Health care almost always begins with a diagnostic work-up: listening to the patient's complaint and history, examining the patient, and testing. It's the point when the physician determines, via some form of observation or measurement, that there's been a change in the patient's anatomy or physiology. And in many cases the news of a diagnosis from the physician changes the patient's life. The scope of diagnostic testing can be quite broad, including screening for disease or predisposition to disease in the general population or those assumed to be at low risk, tests applied to individuals who are high risk or symptomatic to confirm a diagnosis, staging tests for when the diagnosis is known but the extent of disease is not, and monitoring of the disease course or effect of therapy.



WHY CARE ABOUT DIAGNOSTICS?

Diagnostic testing plays a vital role at the point of care. A number of trends are drawing attention to advances in diagnostic technology and what they indicate for future utilization and the cost of health care.

In assessing health status, physicians rely heavily on simple diagnostic procedures such as measuring blood pressure, which occurs in nearly half of physician visits. According to the National Ambulatory Medical Care Services Survey, diagnostic testing and screening services were ordered at 83 percent of doctor visits in 2001. Though clinical chemistry has traditionally been the dominant form of diagnostic technology, clinicians have enthusiastically adopted advances in diagnostic imaging, naming MRI and CT scans as the most important innovations of the last 50 years.¹

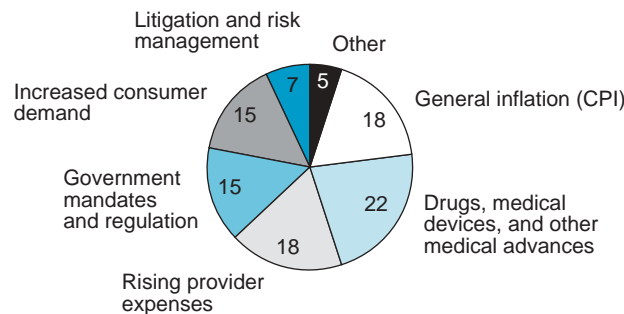
Another area of diagnostic innovation that is expected to transform health care in the future is the burgeoning field of molecular diagnostics, the market for which has been growing quickly at 30–50 percent per year, as knowledge about the human

genome is applied to the tests used in the development of new therapies.

In response to technological advances, health care payers will face the tricky task of paying for expensive diagnostic innovations and high-quality care while trying to keep health care affordable. In addition to greater demand for technology, technology itself increases health care costs. As a primary driver of cost increases, drugs, medical devices, and other medical advances are responsible for 22 percent of the increase in health insurance premiums (see Figure I–1).²

Blue Cross Blue Shield Association (BCBSA), for example, recently reported that the cost of diagnostic imaging will increase by roughly \$20 billion from 2000–2005 and in vitro diagnostics by roughly \$15 billion over the same time period. BCBSA also reports its per member per month expenditures for CT scans and MRIs have increased by 45 and 47 percent, respectively, over two years. Payers assess the cost–benefit tradeoff with many new innovations, especially those that are expected to generate high utilization or high costs and raise questions of how

Figure I–1
Contributors to Health Care Cost Increases
(Percent share of health care cost increases)



Source: PricewaterhouseCoopers, American Association of Health Plans, April 2002.

much incremental improvement is worth paying for and whether improved health outcomes result.

Finally, consumerism is increasing demand for testing. From 1992 through 2001, visits with any mention of a diagnostic and/or screening service increased by 28 percent. Consumer-driven, self-pay CT scanning at free-standing centers has made headlines as both an important way for individuals to take control of their health and as an unethical practice that preys on individuals' fears and generates unnecessary follow up to false positive tests. The more we learn about genetics, the more likely it is that CT scanning for asymptomatic people today will be joined by predisposition genetic testing and genomic profiling. Though there are many medically necessary reasons for genetic testing, there are also hints at the beginning of a commercial genetic testing industry for non-clinical conditions, such as nutrition optimization and healthy lifestyle promotion. Though genomic profiling services may not be ready for prime time yet, current advertising of genetic testing services and the potential of commercially available genetic profiling raise a number of ethical and policy challenges for the future.

THE IMPACTS OF THREE CLASSES OF DIAGNOSTICS ON FOUR CARE SETTINGS

This report, *A New Era of Diagnostics*, examines emerging trends in three diagnostic technology classes.

- Imaging
- Clinical chemistry
- Molecular diagnostics

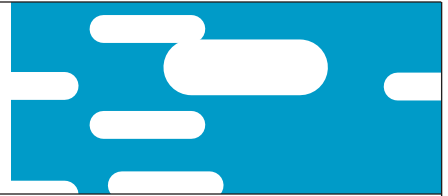
Beyond technological innovations happening across the care spectrum, this report also explores the ways in which these innovations are altering the delivery of care. Specifically, we examine the likely impacts that diagnostic technologies will have in four key markets or care settings.

- Hospitals
- Reference labs
- Physicians' offices
- Patients' homes

Along the way, we look at how payment pressures will affect adoption of new diagnostic technologies and how high the regulatory hurdles may be. We also discuss the importance of consumer-driven demand for the future of diagnostics and take a special look at the coming shift toward ubiquitous testing.

Payment Pressures: The Cost–Benefit Tradeoff of New Technology

1



Despite steady advances in technology, no new technology emerges in a vacuum. Perhaps the most important consideration is that every new technology must be paid for. The pressure for payment influences which new diagnostic technologies are discovered, developed, disseminated, and delivered to patients. This chapter examines how the need to balance costs and benefits at every step affects the ultimate diffusion of new diagnostic technologies.



1. Payment Pressures: The Cost-Benefit Tradeoff of New Technology

COST CONTAINMENT AND REGULATION LIMIT TECHNOLOGY DEVELOPMENT AND COMMERCIALIZATION

In the current environment of health care cost containment, payers have focused on the cost of diagnostic testing. Reimbursement policy for testing has yet to, and may never, catch up with technological advances. Instead, payers are focused on driving down the cost per test, which has had a detrimental effect on R&D spending by developers of diagnostic tests. In the future, payers will create deterrents for use of the most expensive technology. Today, they are charging higher co-pays (\$100) for expensive scans and mandating robust scrutiny for big-ticket items, such as requiring evidence of a family history of three generations of disease occurrence before paying for genetic testing.

The cost-benefit analysis and regulatory hurdles in developing a molecularly based diagnostic often dissuade developers away from diagnostics toward the clearer market of therapeutic applications. The high costs of validating a disease marker for FDA approval and the lengthy lag time between the introduction of a new marker and its widespread adoption by the clinical community are often key factors in discouraging companies from entering the diagnostic marketplace. There is also a significant gap from the date of approval of a new test to the implementation of coverage and reimbursement. Economic benefits of new tests over existing tests are often unclear, an ambiguity that inhibits investment.

REIMBURSEMENT ALSO LIMITS DIAGNOSTIC TECHNOLOGY ACQUISITION

New technology adoption requires access to capital and operating funds. Ensuring reimbursement will be a crucial requirement for technology adoption for hospitals and physicians. As reimbursement levels for all services get squeezed in an era of limited

health care resources, CEOs will need to rationalize to their CFOs and board members that capital investments in new technologies are justifiable, both economically and clinically. Utilization of new technologies and what's defined as "medically necessary" will need to be carefully considered in order to justify large capital outlays for new technology and the ability to amortize financing across a sufficient volume of patients. For example, point-of-care-testing can be relatively high-cost for low patient volumes, vis-à-vis testing in a centralized laboratory.

In the case of hospitals, these financing and business model questions are particularly important. Increasing levels of charity care for the uninsured will adversely impact hospitals that are dependent on strong bond ratings. As technology becomes more complex, especially with the rise of digital systems integration, more hospitals could turn to lease use and turnkey solutions that are volume-dependent as a financing option when they can drive utilization. Innovative models for financing acquisition of new technologies will be in demand, and return on investment will be calculated in new ways going beyond life cycle costs.

REIMBURSEMENT AND UTILIZATION

The high cost of new, complex diagnostics will be a damper on their diffusion. Third-party payers will painstakingly analyze the ramifications of new tests, from the cost of the test itself to the cost of treatment associated with the disease or condition. When they choose not to cover the cost of that new test, the financial burden would then fall on the consumer. Therefore, another likely brake on growing demand for diagnostic testing and lab services will be the consumer's willingness to pay for tests that aren't covered by third parties—or that command a very high co-payment. Beyond responding to the tiering that results from higher co-pays, consumers and

advocates will become increasingly educated and active in their pursuit of innovative and experimental technology.

TESTING TO ENSURE APPROPRIATE TREATMENT

When pharmacogenomic testing takes hold as a standard practice, payers will also take advantage of its ability to target and monitor therapeutic efficacy. More testing and monitoring will drive up cost in the short term but decrease costs in the long run by identifying patients for whom expensive therapies are ineffective. This could spell the end of the blockbuster drug use model as we now know it where even an expensive drug is prescribed for a patient without ascertaining whether it will work or is working after it's in use for a while. New models will slowly evolve, where some drugs will become life-lines and therefore command premium prices and others will be clinically indicated based on genetic characteristics and therefore across new diseases.

Unnecessary testing increases costs directly and indirectly through the detection of potential diseases that may never manifest clinically but, because they are detected, may invoke a treatment regimen. Yet, relatively inexpensive testing can also lead to earlier, more efficacious, and therefore less expensive workup or treatment. For example PET scans may reduce the need for expensive biopsies for lung cancers. Early diagnosis and monitoring may incur increased short-term cost of treatment yet result in the termination or modification of ineffective treatments. The economics and ethics of earlier diagnosis are still evolving.

Seeing into the Future: Diagnostic Technology Forecast

2



Diagnostic technology is improving our ability to assess what's happening inside our bodies more precisely and more dynamically. Improvements are bringing static measures to life and in new clinical contexts.



2. Seeing into the Future: Diagnostic Technology Forecast

GENERAL TECHNOLOGY TRENDS

The power of pattern recognition and influence of information technology (IT) stand out as overarching themes in our technology forecast. With the convergence of IT and clinical technology, the trends of miniaturization and decreasing cost with increasing computer power have increased the power and functionality of many diagnostic technologies while decreasing their size. (For more, see the sidebar, “Accelerating Forces Driving Biotechnology.”) The application of IT to clinical technology takes on even greater importance when considering advances in molecular science. It has facilitated new research and discovery platforms that allow for the capture and analysis of more data much more quickly and thoroughly than ever before. Some implications of these broader trends are:

- Miniaturization has translated into smaller, portable but powerful devices, which mean that imaging and point-of-care lab testing devices can be distributed among many specialties and care sites and can be used in new ways.
- A countervailing trend to decentralized measurement and image acquisition is the centralization of measurement interpretation, particularly for imaging and complex tests, that will be facilitated by large, robust IT and broadband telecommunications infrastructure in the future.

What follows is a summary of advances in three classes of diagnostic technology: imaging, clinical chemistry, and a subset of clinical chemistry that’s promising enough to deserve its own treatment, molecular diagnostics.

ADVANCES IN DIAGNOSTIC IMAGING

Recent advances in medical imaging offer clinicians greatly enhanced and detailed views of human anatomy and much improved visualization of normal and abnormal human physiology using less intrusive and

faster imaging devices. MRI, CT, ultrasound, and nuclear and optical imaging have all benefited from improvements in the power and functionality of energy sources, detector design, detection analysis assistance, storage, and the display of the images, with the greatest advances occurring in CT and ultrasound. Imaging is being used earlier in the clinical encounter for quicker turnaround time and in more care settings, such as the emergency department (ED) and the physician’s office.

Drivers and Barriers to Adoption

Expanded use of imaging and changes in physician training will help to drive the adoption of imaging technologies, while the problems associated with data overload, capital availability, and staffing may slow their adoption.

Expanded Use of Imaging

Imaging was primarily a diagnostic tool but is now also being used for therapeutic purposes. Diagnostic imaging is used in image-guided surgery for biopsies and increasingly to guide surgical instruments in minimally invasive surgery. In addition, imaging has been shown to provide an objective and early means of determining response to treatment, for example, using metabolic or functional imaging to visualize the effectiveness (or lack of it) of chemotherapy.

Physician Training

As technological advances in imaging have expanded diagnostic precision, physicians have come to think of imaging as, if not a direct extension of the physical examination, as a rapid means of “ruling in” or “ruling out” a suspected condition. In medical schools there has been a decrease in teaching of physical diagnosis and an increase in training related to the use and interpretation of diagnostic imaging devices, such as the handheld ultrasound and portable X-ray.

ACCELERATING FORCES DRIVING BIOTECHNOLOGY

Biotechnology development has become increasingly dependent on information technology development. Technical forces described by Moore's Law and Metcalfe's Law that have proven true for computing will also apply to biotechnology (see Table 2–1). Also, the "Law of Finite Biology," coined by Genomic Health CEO, Dr. Randy Scott, at the Institute for the Future's 2003 Health Horizons Fall Conference, *A New Era of Diagnostics and Personal Health Information*, describes the accelerating pace of biotechnology toward facilitating personalized medicine.

Table 2–1
Forces Driving IT and Biotechnology

	What does it mean for computing?	What does it mean for biotechnology?	When will it happen?
Moore's Law			
Transistor density on integrated circuits doubles every couple of years. Exponential growth and ever-shrinking transistor size result in increased performance and decreased cost. ³	Miniaturization of computing tools, which become simultaneously cheaper and more powerful.	Cheaper and more powerful tools for genome sequencing, DNA micro-array, genetic analysis, and so forth.	In play now. DNA sequencing cost has halved every couple of years since 1996.
Metcalfe's Law			
The usefulness, or utility, of a network equals the square of the number of users. ⁴	The Internet is based on the idea that linking people together creates value.	Future of large, high quality, clinical databases that link patients together so they can see how their disease pattern correlates with others and tailor information.	Ten years from now when genomic info becomes more readily available to individual consumers.
Law of Finite Biology			
If you have a finite set of pieces that fit together in an integrated fashion, with each piece you put into the puzzle, you accelerate toward solving the puzzle. ⁵		The human genome is finite. The more we learn about our DNA, RNA, and proteins, the faster we'll get to all there is to know.	Twenty years from now. The mapping of the human genome was like getting the puzzle pieces out of the box.

Source: Institute for the Future; Dr. Randy Scott, CEO, Genomic Health.



2. Seeing into the Future: Diagnostic Technology Forecast

Data Overload, Capital Crunch, and Staffing Shortages

One major barrier that may slow the adoption of imaging technologies, especially in hospitals, is the huge amount of data that digital imaging creates. The creation of large digital archives, recently even further expanded by input from an expanding number of multi-slice CT scanners, will require significant infrastructure support in the form of picture archiving and communications systems (PACS), IT systems, display technology, processor power, and so forth. Concomitant capital investment in imaging equipment and the space for the equipment will also be disruptive to today's radiology departments. And finally, a shortage of radiologists and imaging technicians will serve as an additional barrier to adoption for hospitals.

What Imaging Technologies Will Look Like in the Future

Computer-assisted diagnosis and pattern-recognition capabilities will expand the use of diagnostic imaging, and improvements in imaging technology will also result in expanded criteria and indications for its use. 3D functional images will add a new dimension of systemic context and integration into surgery. Another future use will be the bundling and overlaying of multiple modes of imaging as well as imaging with other diagnostic modalities such as genetic testing to confirm diagnosis and monitor treatment.

Multi-Modality Imaging Brings Anatomy and Physiology Together

We can expect greatly expanded use of functional MRI and PET scanning for a range of conditions and applications. Functional/molecular imaging portrays specific molecular entities in applications ranging as widely as oxygen consumption in the brain to molecular indications of cell death within tumors or tissues. With new molecular imaging agents for both

PET and MRI scanning, the applications of molecular imaging will expand even further for both diagnostic and therapeutic purposes.

Diagnostic imaging and digital technology will be used in telemedicine to bring imaging capabilities to remote locations such as rural health care settings, nursing homes, and prison populations and in mobile applications, such as ambulances. Images can be obtained by technicians and instantly transmitted via PACS to a central location, often a roomful of radiologists, many of whom are cardiac, gastrointestinal, pulmonary, or neurologic specialists, for expert interpretation and rapid transmission by landline or electronic means directly to the responsible physician. The same pod of radiologists will be serving hospitals within hospital systems, inner-city clinics, and other locations in a trend that is gaining many advocates. The advantages are two-fold: first, it is one means of compensating for the shortage of radiologists, and second, interpretation is at the same time rapid and expert.

We can expect turf battles over which specialties are the most appropriate to use imaging technologies. With imaging being used for interventional, endoscopic, and office-based procedures, showing up in the ED, cardiology, orthopedics, gynecology, and surgery, in the ICU and at the patient's bedside, a variety of individuals with varying levels of training will be interpreting scan results. Pattern-recognition software and computer-assisted analysis for detection and diagnosis will help narrow and focus the range of interpretation possibilities, but radiologists will claim that other specialists aren't adequately trained to interpret scans. Non-radiologist specialists typically know little about imaging outside of their narrow field of interest, but familiarity with radiologic interpretation in a single medical specialty offers an overriding advantage to both specialists and their patients, hence the evolving trend.

ADVANCES IN CLINICAL CHEMISTRY TECHNOLOGIES

Laboratory medicine dates back to the 19th century when chemical analysis of urine and feces was performed in the hospital, office, or home. Hospital labs developed into centralized departments in the 1950s, and improvements were made in the range of diagnostic tests and their precision and accuracy. The growth of laboratory automation evolved with successively more sophisticated chemical analyzers and reagents, expanded panels, and, later, with the addition of automation and bar coding. Today's entire laboratory operation has gained additional efficiency by the integration of computerized laboratory and hospital information management systems.

Drivers and Barriers to Adoption

Increasing demands for efficiency and immediate test results in urgent-care situations will drive the adoption of imaging technologies, but resistance from central labs may slow their adoption.

Demand for Efficiency

Efficiency will be a major driver for further laboratory automation and use of point-of-care testing. Like other hospital departments, labs are under pressure to reduce costs. Labor currently constitutes about 60 percent of the total cost of laboratory services. Automation could decrease lab staff by 25–50 percent. But, only the larger labs will realize the greatest efficiencies provided by automation. Labs will seek to increase efficiency by providing consistent high-speed and high-volume sample throughput to enhance testing capabilities. This push for increased efficiency will also drive labs to move disruptive STAT and priority testing out of their workflow.

Need for Test Results in Urgent Care

Demand for immediate test results for urgent care will be a driver for its diffusion in settings such as the ED for patients with chest pain. Point-of-care testing fits well with the patient-focused model of care. Yet hospitals and payers will seek to manage demand and ensure only medically appropriate testing is done because of the perceived higher cost. When used appropriately, the benefits of immediate diagnosis, decision, and action will improve care and almost certainly lower overall costs through better outcomes and more timely and efficient use of other resources. There will be a struggle to rationalize the use of point-of-care testing until the price of disposables drops significantly, but predictably, costs will fall as testing volume increases and new suppliers enter the market. In the meantime point-of-care-testing companies will compete with rapid response laboratories that can turnaround diagnostic tests in 30 minutes.

Resistance to Decentralization

Directors of some central labs will resist this transition to testing outside of their direct supervision. Their principal arguments center in two areas: relative cost and accuracy. Although the cost of point-of-care testing will never compete with high-throughput chemical analyzers, it's unknown how the derivative cost reduction of rapid medical decisions and directly related improved outcomes (for example, earlier intervention, reduction of patient apprehension waiting for test result) might offset the unit cost of testing. The accuracy has to do with the technology itself and with the qualifications of the person, typically a physician or nurse, as a "technician." Regulatory bodies, principally the FDA and state laboratory oversight agencies, dispute this latter argument.



2. Seeing into the Future: Diagnostic Technology Forecast

What Clinical Chemistry Technologies Will Look Like in the Future

Hospitals and regional reference labs will continue to seek further reductions in laboratory expenses. Mechanisms that will help laboratories meet the new paradigm for the delivery of diagnostic services include centralization of medical/laboratory systems, judicious application of point-of-care testing, consolidation of diagnostic testing into fewer workstations, and implementation of laboratory automation. Further decreases in labor costs, and thus cost per test, will occur from the implementation of new technologies and new automated instruments with consolidated test menus that can handle large test volumes.

Most importantly, the laboratory system of tomorrow will be highly dependent upon information technology, both to control laboratory automation and to handle the data flow from point-of-care-testing systems on a real-time basis. In this laboratory system of the future, large centralized automated laboratories will perform esoteric tests and some routine tests. The traditional critical care/STAT laboratory will disappear and be replaced with point-of-care-testing technologies that use non-invasive, minimally invasive, and in vivo technologies. Hospital networks will have one or more strategically located, centralized laboratories allowing some hospitals to rely solely on point-of-care testing for in-house testing. All testing results whether performed in the central lab or at the point-of-care will, eventually, flow automatically into the electronic medical record for instant access by physicians and other health care workers.

ADVANCES IN MOLECULAR AND GENE-BASED DIAGNOSTICS

The diagnostic technology with the greatest promise (and uncertainty) is molecular diagnostics. Molecular diagnostics hold the promise of risk susceptibility identification and preventive intervention through behavior changes and drugs. For pre-symptomatic genetic diagnosis, one of the best examples is testing newborns for metabolic disorders, where intervention in some cases can avert serious consequences. In other conditions, molecular testing such as pharmacogenomic testing may allow the selection of the most appropriate drugs. Further, molecular testing will be used to provide a certain diagnosis of a disease including type of tumor.

Drivers and Barriers to Adoption

Adoption of molecular diagnostic technologies will be spurred by the promise of better drugs, but technology complexity may dampen their growth.

The Promise

The biggest driver for molecular diagnostic technology is the promise of better preventive and therapeutic drugs. The primary effort is in linking gene mutations and their products with specific diseases. This effort, combined with advances in bioinformatics that incorporate large quantities of research data, advance our scientific understanding of complex disease processes and identification of genetic targets and potential areas for advances in drug development and, eventually, treatment of diseases. Pharmaceutical developers who bundle their products with molecular diagnostics will be delayed as they establish a market for their drugs and gather the amount of data clinical buy-in requires. Other than the early examples of Herceptin and Gleevec, the promised pharmaceutical product stream that will result remains far off in the future.

Technology Complexity

Genetic testing is a complex process, and the results are dependent on replicable laboratory procedures, the clinical validity of the test itself, and accurate interpretation of the results. Technologies used for taking genetic testing further toward personalized medicine include emerging microarray and microfluidic devices that are highly complex from both the engineering and chemical perspectives, advances that often magnify the overall complexity of a given analytical technology. Processing information at the level necessary to interpret large amounts of genetic-screening data, for instance, requires instrumentation of greater sophistication than previous generations of diagnostic instruments—and usually in a format that operates invisibly to the user.

What Molecular Diagnostic Technologies Will Look Like in the Future

The most dramatic expansion in diagnostic testing over the next 3–5 years will happen in molecular diagnostics. Molecular diagnostics are currently in use for a number of diseases, such as cystic fibrosis and sickle cell anemia, and they will expand to include many others, such as incipient hypertension or stroke. Advances will take us from preventive, prenatal, or newborn screening in at-risk populations such as those who are carriers of genetic disease (e.g., autoimmune disorders and cystic fibrosis) to the future of population screening and predictive testing to determine individual susceptibility to more common adult-onset disorders such as heart disease, cancer, and diabetes. Preventive medicine can take over after identification predisposition testing to modify an individual's health behaviors and in some cases to begin a preventive drug regimen.

Primarily comprised of genetic and proteomic testing, advances in this field are from applications of the technology used for molecular biology

research. As basic scientists from research institutions and pharmaceutical companies search for new and improved methods of drug discovery and development, they often create probing technologies that help them better understand the pathology itself, thereby laying the groundwork for new diagnostic technologies. For example, infectious-disease testing, where fully automated laboratory systems have been developed, utilizes some of the same technologies used in molecular diagnostics and, in fact, the dominant genetic tests outside of reproductive testing are for diagnosing HIV and human papilloma virus (HPV). Other opportunities are presented through the discovery of new genetic markers, which are often developed initially as tools for life sciences researchers but find their first clinical use in the form of molecular diagnostics.

Though great strides have been made in molecular diagnostic technologies such as genotyping, identifying mutated single nucleotide polymorphisms (SNPs), and viral load monitoring, the current area of exploration relates multi-gene patterns and interactions (genomics as opposed to genetics—that is, genes working in concert versus analysis of single genes isolated from modification by gene expression elsewhere in the genome). The hottest area today is the analysis of normal and abnormal patterns for the identification of diseases such as ovarian cancer. Another area of recent discovery is in the link between behavior and environment as we learn more about genetic influences that predispose individuals to environmental factors and, for many conditions, determines health risks in certain environmental circumstances.

Biomarker discovery is an area of focus for many academic and pharmaceutical researchers. Biomarkers are molecules that indicate an alteration in physiology from normal. Biomarkers that specifically and sensitively reflect a disease state can be used



2. Seeing into the Future: Diagnostic Technology Forecast

for diagnosis as well as for disease monitoring during and following therapy. Those that can be used to identify and specify pathologies such as cancer and cardiac disease will be sought after by diagnostic technology developers for their therapeutic implications. Similarly, biomarkers will be investigated by life science researchers seeking to understand the pathological process.

Over the next five years, pharmacogenomics will be used to probe whether a drug will be efficacious in a patient and whether it will be safe. An example of pharmacogenomics is the measurement of cytochrome P-450 enzymes that are linked to the metabolism and drug interactions of approximately 40 percent of pharmaceuticals currently in use. For an individual considering a traumatic and painful course of chemotherapy, having the capability to determine whether the therapy will work will have a strong influence on her decision.

Development of genetic testing technologies, such as microarrays and high-throughput newborn screening using tandem mass spectrometry—both technologies that can pinpoint pre-symptomatic disease—have mostly come from exploration of new technology applications in life sciences research or drug-discovery applications, and most of the clinical testing is taking place not in clinical laboratories, but in research settings. The biotechnology instrumentation in development and use in life sciences research now may shed light on future clinical testing technology, for example, the identification of new molecular markers, combined with the application of complete automation to laboratory segments that are lacking it today, may offer the growth spark needed to advance the field.

As our understanding of biology improves with concomitant improvements in the precision and expanded functionality of diagnostic technology, we will continue to struggle with the technology transfer

into clinical practice as well as the economics and ethics of how to implement them for earlier diagnosis and intervention and ultimately better health care and health outcomes.



Regulatory pressures also will affect the future of diagnostic development and availability. Labs remain the sanctioned, and therefore preferred, setting for most complex tests. Though physicians and other providers may wish to respond to consumer demand for faster testing, the regulatory obstacles may be too high.



3. Regulatory Hurdles

CLIA SLOWS PHYSICIAN ADOPTION

The fear of malpractice litigation and regulatory restrictions will be a barrier for physician adoption of many diagnostic technologies. Effective in 1967, Congress passed the Clinical Laboratory Improvement Amendment (CLIA) after reports of shoddy and illegal practices by medical labs surfaced in the mid-1960s, which resulted in a number of deaths due to missed diagnoses. CLIA had a chilling effect on the implementation of physician-office labs. While new technologies are enabling physicians to overcome fears about the regulatory burden of operating their own labs, many physicians still find the numerous regulations for staffing, quality assurance, and documentation onerous.

GENETIC INFORMATION AND PRIVACY

Recent legislation regarding the handling of genetic information was a long-awaited success for consumer privacy advocates. The Senate passed a bill that would confirm at a federal level what many insurance companies and states have had in place—that health insurance companies may not use genetic information or family histories to deny coverage or set premiums. The measure would also prohibit employers from using such information in hiring or firing decisions. The health insurance industry has argued that the legislation would increase costs without improving consumer protection. Health insurers argue against genetic exceptionalism, where genetic information is given more power than other forms of medical information. They argue that genetic information is just one of many pieces of information they consider when making decisions. But there are many, particularly consumer advocates, who argue that there is special power in genetic information and are comforted by strong regulation of its use.

THE FUTURE OF HOME BREWS

At this time, academic and commercial reference laboratories perform the bulk of genetic tests. These labs develop their own testing procedures or purchase third-party test “kits” or systems. Tests established by a laboratory for its own use are referred to as “home brews,” while off-the-shelf test kits require FDA approval. Available kits contain the necessary reagents to perform a specific genetic test and are considered to be hybrid medical devices because they are packaged instruments that incorporate a biologic material. The availability and capabilities of these kits are expected to grow in the future.

How a test is classified makes all the difference in how it will be evaluated by the FDA. The FDA evaluates genetic tests marketed as kits for clinical validity and utility. The FDA does not regulate tests marketed as lab services, and although the agency states it has the authority to regulate these home-brew tests, it lacks the resources. Furthermore, the FDA does not regulate diagnostic testing performed in a laboratory setting; CLIA, under the purview of the Centers for Medicare and Medicaid Services, provides the regulation for audit and approval of the quality and practice of laboratory medicine.

FDA ASKING FOR PHARMACOGENOMIC DATA

The recent FDA announcement of draft guidelines for the submission of pharmacogenomic data with drug applications met with mixed reviews from the pharmaceutical and biotech industries. Though the guidelines are not yet final, this is the first important step in a move toward requiring data that proves the efficacy of genetic and molecularly targeted innovations over what’s currently in use. As an economist by training, current FDA Commissioner McClellan is a proponent of pharmacogenomic data.

The pharmaceutical industry worries that submitting pharmacogenomic data adds an untenable burden to the clinical trial process that will slow down the approval process and increase the cost of drug development. Essentially, pharmaceutical companies are loath to give the FDA any additional reasons to reject a drug application. Traditional pharmaceutical companies fear this could spell the end of the blockbuster model, as the markets for many drugs will be shrunk by tests that rule out “non-responders.” Therapies with high failure costs, such as cancer drugs, that were used in a “try it and see” model will shift to a “try it and come back in 48 hours to determine whether it’s having the desired effect” or a “test to see if you have the genetic profile to respond at all” model.

Those most immediately affected by this regulation will be pharmaceutical companies like Millennium Pharmaceuticals, whose products depend on diagnostic genetic testing to determine the safety and efficacy of a drug and who will sell the product as a diagnostic/therapeutic combination.



THE SHIFT TOWARD UBIQUITOUS TESTING

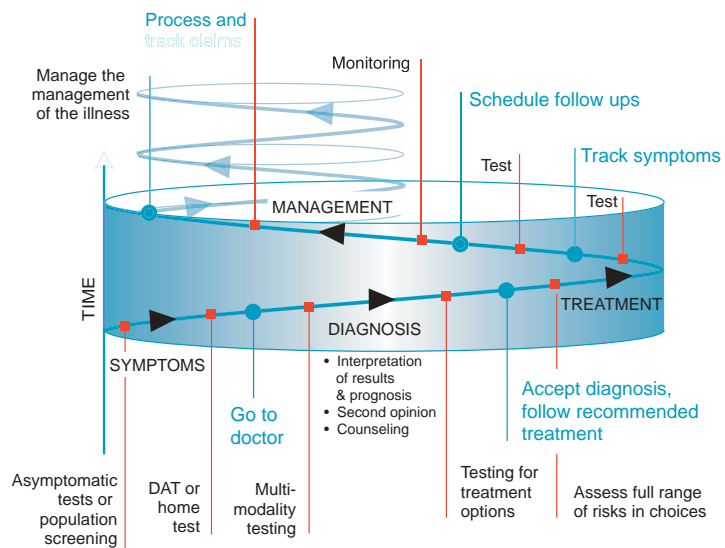
Two key themes—pattern recognition technology and expanding clinical contexts for diagnostics—surfaced during our research that point to a potential future of ubiquitous testing. If and how fast we reach a state of ubiquitous testing will be regulated by important discussions and, ultimately, by decisions of what kinds of testing are appropriate in which contexts and who will pay.

The Power of Pattern Recognition and Information Technology

Diagnostic tests look for results outside the norm. At their core, they seek to find an aberration in a pattern, either between an individual and norms in the population or in an individual over time. Today, advances are being made in the precision of testing, allowing us to detect more subtle aberrations than in the past. These changes are coming through improvements in diagnostic tools themselves and our understanding of systems biology and the biochemical basis of illness. For example, through repeated measurement of one biomarker (for example, prostate-specific antigen [PSA] for prostate cancer or Hepatitis B virus surface antigen [HbsAg] for Hepatitis B) was a sufficient indicator of disease in the past, advances now are in measurements of multiple biomarkers relative to one another (for example, protein profiling for breast cancer).⁶

Moreover, the convergence of information technology and clinical technology now allows for the incorporation of much more diagnostic information into the decision-making process than in the past. Diagnosis is no longer based only on what the individual patient can recall and what the individual physician has observed and memorized or written down. Information on patients comes from more testing sources than in the past and that information can more easily be compared to

Figure SI-1
New Opportunities for Testing Are Being Added Along the Care Path



Source: Institute for the Future

the medical literature or to results for large collections of other patients. As pattern-recognition software improves, clinicians will offload a share of their interpretation to automated analytical assistance; in the future an individual physician's lifetime of clinical experience may no longer be the gold standard of medical judgment.

Though improvements in information technology will lead to concomitant advances in its integration into clinical technology, the greatest barriers to using increasingly "infomated" clinical technology will remain infrastructural—that is, setting up the systems and making necessary social or behavioral changes on the part of clinicians. Information technology systems throughout health care are necessary for the full benefits of many diagnostic innovations, such as state-of-the-art imaging, laboratory automation, and point-of-care testing to be felt. The slow development of comprehensive health information systems due to unclear standards and difficulty integrating many types of data will slow our ability to respond to test results. Even so, some medical groups that are not ready to embrace a full electronic medical record are using disease registries to manage chronic disease. Many of these registries include lab values, an increasing share of which is transmitted electronically.

Expanding Clinical Contexts for Testing

With broader clinical contexts for diagnostic testing, testing no longer appears just at the beginning of the care path. Measurement and monitoring happen across the care continuum, as well as in therapeutic contexts (see Figure SI-1). Testing has four principal uses in clinical settings: screening, diagnosis, staging, and monitoring (see Table SI-1).

Table SI-1
Testing Used in Four Key Clinical Settings

Testing Form	Role in Clinical Care
Screening	A test to detect either asymptomatic disease or a predisposition to disease.
Diagnosis	A test to make a diagnosis when symptoms, abnormalities on physical examination, or other evidence suggests, but does not prove, that a disease is present.
Staging	A test is used to stage a disease when the diagnosis is known but the extent of disease is not.
Monitoring	In a patient known to have a health condition, a test is used to monitor the disease course or the effect of therapy.

Source: Institute for the Future



For example, in pharmacogenomic testing—testing the variability of patient responses to drugs—a staging test may be given after initial diagnosis to determine whether a person might respond to a given therapy. Then a monitoring test might be given to determine whether the therapy is having the desired effect on the patient. As tests improve, allowing for more frequent measuring and monitoring of patients, we may improve our understanding of their evolving health and our chance of recognizing aberrations in their health at an early stage, whether that aberration is relevant or not. Finally, consumer “self-curiosity” and desire to control their own health care experience will result in more home testing and out-of-pocket utilization of testing services. Increasingly, patients and health care providers will no longer want to wait for the manifestation of disease in gross physical symptoms to learn more about it.

At the same time, this greater availability of testing information raises the specter of changing physician–patient relationships. With less emphasis on physical diagnosis and more on test results, physicians’ skills may atrophy and, while patients are more satisfied when technology is used during an office visit, their expectations with regard to the “laying on of hands” as part of the care process may go unfulfilled. In addition to that cultural shift, the quick turnaround of better diagnostic information may severely decrease the time physicians have to consider a patient’s case; as lag time between ordering a test and getting its result decreases, reliance on that test to provide all relevant information will increase.

Ubiquitous Testing Raises Questions of Appropriateness

Several factors are leading to a proliferation of diagnostic testing. On the supply side, as we continue to gain understanding of the molecular and genetic mechanisms of disease, new biological markers will increasingly become the basis for new diagnostic tests. Improvements in testing modalities are leading to earlier and better detection of disease. Health care providers must deal with a slew of available tests and decide which are appropriate in which contexts. On the demand side, fears of missing a diagnosis or of malpractice litigation drive physicians toward practicing defensive medicine, and erring on the side of over-testing. Another driver is the desire of physicians to provide “one-stop” service by ordering a wider array of tests in an effort to speed the patient through the care process. Indeed, up to one-third of tests done in acute hospital settings are likely to be inappropriate in terms of their ability to contribute to the diagnosis and treatment of the patient in question. In addition, more than 10 percent of diagnostic tests in the United States are probably done simply because the results of previously performed tests aren’t available at a subsequent clinical encounter. Other redundant tests are actually part of federally mandated test panels.



Complicating these contending impacts of diagnostic testing are the differing interests and liability fears of health care practitioners, health insurers and purchasers, and especially patients. The emergence of affordable, commercially available, diagnostic testing centers and test kits allow patients to gain information about their health outside the realm controlled by their health insurance plan, but to also make demands on their health insurance based on that outside information. What constitutes appropriate testing and the parameters of where such testing should occur are questions whose answers will profoundly impact health care in coming decades.

Greater testing and the advent of patient-initiated testing are also leading to an emerging discussion about the interpretation of test results and the value of different forms of information. With the implementation of each newly approved test there is an initial period of wide and perhaps even useful variation in its use, interpretation, and treatment implications. Diagnostic tests, such as genetic testing and new imaging modalities, give complicated and sometimes conflicting information about a patient's health status, which require significant interpretation. With multiple readers of test results, contention between interpreters is inevitable, and the role of informed patient preferences in light of complex information communication becomes more important than ever before.



The Impact of Diagnostic Technologies on Clinical Care

4



As new technologies diffuse into the care process, most improve health outcomes significantly while simultaneously increasing the cost of care. Diagnostic testing's role in determining the care path and its continued growth in expenditures makes it a target for cost-containment. When discussing technological innovations in the aggregate, a number of general characteristics determine how a new diagnostic technology diffuses into clinical care settings and markets, whether there's a revenue or reimbursement stream for the innovation, whether it improves the quality of care, whether its utility is easily understood, and whether it improves clinical and workflow efficiency.



4. The Impact of Diagnostic Technologies on Clinical Care

MARKET FORECAST

The market for laboratory diagnostics has been dominated by a small number of large diagnostic test developers, such as Roche Diagnostics, Johnson & Johnson, Bayer Diagnostics, and Abbott Laboratories, and clinical laboratories, such as Quest Diagnostics Incorporated and Laboratory Corporation of America (LabCorp), which combined control approximately 70 percent of the national market for lab specimens from physician's offices. Given poor overall market conditions, both sectors have done relatively well and some companies have even experienced significant growth over the last few years. Growth came in two forms, 1) the successful approval and release of new tests by technology developers, and 2) the acquisition of smaller biotech and independent lab companies by bigger labs.

Indeed, the last few years have seen massive restructuring of the clinical laboratory industry. The two industry giants in the United States, Quest

Diagnostics and LabCorp, have made multiple acquisitions, adding to their technology portfolio and bringing biotechnology capabilities into their businesses (see Table 4-1). Quest and LabCorp have both come from behind in the last three years. With traditionally low reimbursement for labs corrected upward by payers, more sophisticated management, an aging population driving up testing frequency, and sector consolidation, which eases price competition and allows them to take advantage of economies of scale, they now lead the laboratory industry and are positioned to play leading roles in a shifting health care system.

However, they've also drawn the attention of the Federal Trade Commission, which questioned the effect of such massive consolidation on the competitive nature of the industry. With 180 diagnostic/biotechnology collaborations generating \$350 million in 2002, labs are probably near the end of their feeding frenzy and will look for innovative collabo-

Table 4-1
Top Labs Most Active in M&A
(Value of top-five M&A transactions in the diagnostics industry in 2002)

Aquirer	Aquired	Value (Millions)
Quest Diagnostics	Unilab	\$1,100
LabCorp	Dynacare	\$698
LabCorp	Dianon	\$598
Quest Diagnostics	American Labs	\$500
Johnson & Johnson	Tibotec-Vicro NV	\$320

Source: Windover; Burrill & Company.

Table 4-2
Diagnostics Forecast: Clinical Chemistry Dominates but Molecular Diagnostics Growing
(Percent share and value of ... market)

	Share of Market (Percent)		Value of Market (\$ Billions)	
	2002	2006	2002	2006
Clinical chemistry	78.6	70.6	26.3	27.3
Anatomic pathology	18.6	19.8	6.3	7.7
Molecular diagnostics	3.8	9.6	1.3	3.7

Source: Thomas Weisel Partners LLC; Burrill & Company.

rations, rather than acquisitions, to drive growth in the future.

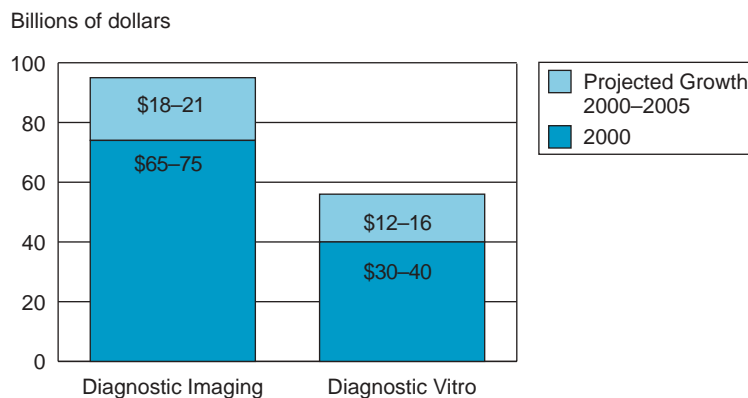
For both molecular-testing sectors, growth is expected to continue with the development and incorporation of complex and expensive molecular diagnostics into clinical care (see Table 4–2). There were 1 million genetic tests conducted in 2002 and that number is expected to grow to 10 million by 2006.⁷ Most genetic testing today occurs in infectious disease testing for HIV, hepatitis, and HPV to assess viral load and for blood banking. Expansion areas include identification and classification of cancers, predisposition testing, and genetic and proteomic profiling of multiple disease markers. Test growth is limited by the availability of therapeutics for the disease state. For example, ApoE testing has been very limited due to the lack of preventative therapy for Alzheimer’s disease.

The diagnostic imaging market is measured in two ways. System sales, which were approximately

\$14.5 billion in 2002, are projected to reach \$16.5 billion by 2006. Thanks to their technical simplicity, availability, and affordability, conventional X-ray- and ultrasound-based systems are the imaging tests most frequently performed. Together, these two tests account for over 50 percent of the total worldwide imaging market. Sales of diagnostic imaging equipment in the industrialized nations (that is, United States, Europe, and Japan), account for over 80 percent of the worldwide market.⁸ The second measure is the one used by payers to describe the health expenditures that go toward paying for diagnostic imaging services (see Figure 4–1)

In this chapter, we focus on the impacts that advances in imaging, clinical chemistry, and molecular diagnostics will have on four health care delivery sites: the hospital, the physician’s practice, the laboratory, and the home.

Figure 4–1
Diagnostics Expenditures Could Near Ten Percent of Health Care Dollar
(Value of ... health care expenditures)



Source: Booz Allen Hamilton analysis of Medical and Healthcare marketplace guide data.



4. The Impact of Diagnostic Technologies on Clinical Care

IMPLICATIONS FOR HOSPITALS

Diagnostic technology in hospitals resides in a larger ecology of users, other technologies, work practices, institutional policies, and legal, socioeconomic, and cultural factors. For example, spiraling health care costs, looming staff shortages, and capacity management are among the top concerns of hospital administrators. Yet, except for big-ticket items, most hospital executives do not yet understand that technology evaluation is a key part of the hospital's mission; strategy, finance, regulatory constraints, and the demands of three key stakeholder groups (physicians, payers, and consumers) all contribute.

Among the three technologies under consideration here, clinical chemistry has the longest history. Today, clinical laboratory data are used in making over 60 percent of all clinical decisions in the hospital setting. In the current operating environment of “faster is better,” the main driver of the use of point-of-care testing is a desire for immediate access to information, and the consequent downstream workflow and cost efficiencies. Whether due to organizational barriers or lack of information, centralized laboratory testing has not satisfied this need. Thus, point-of-care testing is a direct threat to the hospital-based lab. The complexity and cost of molecular diagnostics makes it likely that some hospitals will outsource a significant share of such services to reference labs.

Diagnostic imaging, including both traditional radiology and newer modalities, has also had a long history of association with health care, mostly in acute care or hospital settings and is a major capital expense for hospitals. The emergence of affiliated and commercial imaging centers has created opportunities for joint ventures and threats to existing service lines and revenue streams for hospitals.

As new diagnostic technologies become available, hospitals will face several issues, in particular, around centralization and fragmentation of some

services, an increasingly acute patient population, the speed of diagnosis, competition, and the integration of diagnostics and care.

Centralization and Fragmentation

Watch for the hospital lab to “shrink” or become regionalized. In some metropolitan areas, centralized reference labs have already emerged to conduct unusual or complex tests. Opportunities to develop joint ventures and partnerships to diversify the portfolio risk of adopting a larger number of new technologies will exist.

While centralization will evolve at one level, so will fragmentation of lab services at the point of care and fragmentation of channels to reach out to consumers. Testing will happen in more, and more diverse, locales—and not just in typical health care sites. Anticipate more testing links in retail environments that are sponsored by hospitals. Imagine Wal-Mart and Costco as headquarters for community health initiatives.

The Challenge of Higher Acuity

Hospitals will be managing an increasingly acute patient population, putting even more pressure on limited capacities. Though patients in ICUs are thought to have a high proportion of unnecessary “routine” tests, technologies can be adopted to better manage sicker and sicker patients across the care continuum.

Faster and Faster

The ED, ICU, and hospital outpatient clinic will get information back to the physician and patient sooner, enabling quicker diagnoses and therapeutic interventions that will enhance health care quality and outcomes. However, depending upon the type of test, a quick turnaround can also add stress. In a recent article about rapid HIV testing, a counselor talked about the value of time to ruminate about a test result

before it comes back. This time lapse can be valuable for patients, to think about what a diagnosis might mean for them, and for clinicians, to observe the patient holistically, particularly with regard to mental status.

Turf Battles

In a growing number of communities, hospitals and physicians are engaged in a “medical arms race” in which specialists develop and operate in surgical centers and hospitals that compete with existing community hospitals. New diagnostic technologies will present similar opportunities and threats to the hospital and its admitting physicians. Where will these technologies reside? There will doubtlessly be physicians who will seek to own the diagnostic and clinical processes as they have done with specialty hospital procedures. Economic drivers will also play a role for physicians, as it’s been suggested that most of the difference in profit margin between investor-owned and not-for-profit hospitals comes from the ordering of diagnostic tests. Hospital-based radiologists and laboratorians will find themselves challenged by a growing array of non-hospital and point-of-care-testing providers.

Integrating Diagnostics and Care

Information technologies in hospitals are beginning to integrate with care technologies, for example, point-of-care medical management for infusion therapy. There will be a convergence of technologies at the patient bedside, including diagnostic medical devices, bar coding, clinical information systems including both “hard” data from sensors and “soft” data such as patient preferences, and knowledge-based, decision-support tools. Together, these systems will interact with the hospital’s information system and electronic medical record. The largest hospital information system vendors, such as Cerner, Eclipsys, GEMS, IDX, McKesson, and Siemens are in place to build these capabilities.

IMPLICATIONS FOR PHYSICIAN PRACTICES

For the physician, a matrix of innovations, rather than any single technology, defines health care delivery. In fact, physician practices are supported by this technology matrix, where physicians’ decision making is enhanced through technologies provided by the hospital, laboratory, imaging center, and other specialized clinical sites. Doctors’ offices and clinics in effect function as a portal for information exchange and access between patient and the health care system.

Physicians’ choices of when to use the diagnostic technologies described above will be driven primarily by their community’s standard of care and by what will give them the information they need to come to a diagnosis. They will look for technology that helps them make decisions and communicate with their patient at the point of care. Technology developers that recognize and facilitate response to the patients’ questions at the point of care will win loyalty by creating more satisfied patients and physicians. They will also nurture the physician–patient bond. Answering patients’ crucial questions will help add high-touch to high-tech.

Physicians will wish to reap benefits of integrating information technologies to support clinician decision making. Broadband connections will enable information sharing with other clinicians, institutions, and consumers, especially for digital imaging and telehealth applications. Clinical test results could be seamlessly and automatically recorded into electronic medical record systems where they have been adopted in physician practices.

Keeping up with the unrelenting torrent of technological advances will be very difficult and time consuming for the average physician as complex new diagnostics are developed and especially if genetic testing is widely implemented in primary care. The medical profession is not ready for genetic testing and doesn’t do a good job of communicating



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probabilistic risks, which genetic counseling entails. The vast majority of primary care physicians have insufficient knowledge of genetic medicine to know when to refer patients for testing. The current medical school curriculum does not provide clinicians with the interpretation and counseling skills necessary for use of widespread genetic testing, although that is beginning to change.

Typically, labs have introduced new diagnostic tests and educated doctors on their uses. With emerging molecular diagnostic tests, this will be more challenging. Professional societies will take the lead in educating their constituents in genetics and genomics with an appropriate clinical focus as well as pushing for changes in medical school curricula for future generations of physicians. However, until physicians welcome and receive such education, lack of awareness of how emerging tests fit into the clinical decision and treatment processes will remain a significant barrier to adoption.

Many new technologies and processes—such as genetic testing, interpretation, and counseling—require time for physicians and patients to discuss implications and interventions. Yet both physicians and patients are often challenged by time pressure and short attention spans. Patients, too, when faced with complex clinical or health behavior decisions, look for “yes/no” answers where there may not be such a clear-cut response to the results of a test.

Finally, most physicians remain in small practices of fewer than six physicians. As small businessmen, they are constantly worried about their liability and business risks. Though there’s been a fair amount of state legislation attempting to address sky-high malpractice insurance rates, many physicians will continue to over test in a defensive-medicine mode. This trend will be further enhanced because many also see increased patient satisfaction when tests are used.

Physicians will also face many issues associated with new diagnostic technologies in the future

including fulfilling the continuing need for personalized care, forming new kinds of partnerships, and competing with hospitals.

Personalizing Medicine for Patients

The physician will remain at the heart of the most trusted personal relationship that consumers have with the health care system. Most physicians will want to continue to nurture this relationship and provide a more personalized medical experience for their patients. The adoption of some new technologies—diagnostic imaging and genetic testing among them—will provide the tools for creating more intimate clinical information. On the treatment side, more personalized pharmaceutical therapies will help close the loop on personalized diagnosis, treatment, and monitoring.

A New Generation of Physician Joint Ventures

Physicians will form alliances, as they have done in developing bricks-and-mortar specialty hospitals in the early 2000s. Physicians will group together to share investment—and risk—in new technology ventures. They will also do so to aggregate patient volumes to help lower costs per transaction (for example, test, image, or encounter). At the same time, intense scrutiny by the Office of the Inspector General regarding physician self-referral will discourage cream-skimming of the highest revenue conditions from public and non-profit hospitals.

Physicians Will Compete with Hospitals on a Selective Basis

Physician groups invest in emerging technology areas where they can enhance declining incomes. In particular, the areas of cardiovascular services, orthopedics, ambulatory surgery, and diagnostic equipment will be seen as attractive—and they will compete with hospitals. Physicians and hospitals will

need to reconcile this cooperative–competitive aspect of their relationship.

IMPLICATIONS FOR LABS

The worldview of the laboratory is changing. Diagnostic testing will become an increasingly critical component of care, due to increasing use of technologies such as pharmacogenomic testing and real-time monitoring of chronically ill patients. The quality of care movement in health care has identified more effective use of diagnostic testing—especially at the point of care—as a critical factor for improving

patient care and reducing medical errors in the U.S. health care system. As shown in Table 4–3, “the lab” has already begun to move outside of the hospital and into a broad range of health care locales. Over the next several years, the lab—or, at least, a broader range of simpler clinical lab testing processes beyond glucose monitoring and pregnancy testing—will continue to move into physician offices and consumer homes. At the same time, labs will recognize and continue to nurture their hospital relationships.

In the coming decade, labs will face issues related to becoming an information provider, their role in disease management, branding, and service delivery through retail channels.

The Real Product of the Lab Is Information

Laboratories are critical distribution channels for information. Web-based approaches for clinical informatics are enabling the laboratory to extend its reach to a widening range of sites and improving quality control in the process. This shift in role to information provider is a real opportunity for labs to expand beyond their current services.

That said, risk-averse laboratorians will seek to minimize liability of uncertain new business lines such as genetic counseling if they don’t yet see themselves as information companies. A genetic test that results in a positive or cloudy result could lead the diagnostician at the lab to quickly advise, “Go see your doctor.” A lack of established competency and reimbursement for counseling and interpretation has kept labs away from higher-level interpretation of data, but the potential to broaden their scope into this market is real. Labs increasingly will know more about the appropriateness and availability of increasingly complex tests.

*Table 4–3
Growth in Labs Outside of the Hospital
(Number of U.S. clinical labs by type, 1996–2002)*

Type of Lab	1996	2002	Percent Change
Pharmacy	294	2,276	674
Ambulatory surgical centers	1,162	2,739	136
End-stage renal dialysis facility	1,932	3,417	77
Other*	23,675	31,262	32
Ancillary testing site in health facility	2,279	2,697	18
Physician office	89,667	100,813	12
Skilled nursing facility	13,965	14,728	6
Hospital/HMO	9,871	9,262	-6
Independent	5,769	4,959	-14
Home health agency	8,766	7,485	-15

* Other includes community clinic, rehab facility, health fair, hospice, industrial, insurance, mobility unit, school/student health services, tissue bank, blood bank, public health, and other labs.

Source: Centers for Medicare & Medicaid Services



4. The Impact of Diagnostic Technologies on Clinical Care

Labs Play a Role in Disease Management

Use of point-of-care testing for monitoring the effect of therapies provides benefits—not from the speed of the individual test, but rather from the ability to increase the frequency of monitoring, stop ineffective or harmful therapies, and maintain tighter regulation. For example, frequent glucose monitoring in patients with diabetes leads to better outcomes. For high-risk diseases such as AIDS, the use of lab tests for prognosis is critical. By carefully defining the use of the tests and establishing the link between the tests and outcomes, measuring the outcome of new therapies is possible.

Labs Will Benefit from Branding

With the growing range of locales for lab services and consumers considering direct access testing without a physician prescription, it will be important for lab-service providers to develop branding strategies. For consumers searching for labs, the brand will become a beacon for navigating in a sea of choices. In particular, the brand will become a quality marker when a consumer is operating without a trusted physician or clinician intermediary. Labs will build brand equity through advertising and promotional strategies that connect them to consumer touch points and their motivations to undergo diagnostic testing.

Labs Go Retail

Consumers are increasingly looking for health and health-related products and services in grocery, big box, and other retail environments. As retail formats successfully grow the pharmacy channel, pharmacies will be a major conduit for consumer-facing lab services. In 2003, this concept was launched in Connecticut by the Stop & Shop Supermarket chain's alliance with Quest Diagnostics. Stop & Shop customers can select from a menu of 12 popular health-screening tests, which are processed

through one of Quest's 71 patient service centers located throughout the state. Customers can receive test results online or via mail.

IMPLICATIONS FOR THE HOME

Home is where the health is for a growing number of consumers. The growing self-care movement of individuals taking initiative to care and treat themselves before paying to go to the doctor, coupled with the adoption of broadband-enabled technologies, is driving consumers to use or consider using health technologies at home.

Figure 4–2 depicts of the first-ever character-licensed digital thermometer for consumers. The product incorporates easy to use features into a useful diagnostic technology, coupled with the pop-culture icon perhaps most popular with American children today, SpongeBob SquarePants. This is an example of a product that many kids will want, parents will adopt, and the family will happily use when appropriate. What's new here is that a diagnostic technology is being introduced to all family members as a fun tool for managing health instead of a delicate tool to be kept out of reach of children. Another example of new popular awareness of advances in genetic diagnostics is the award-winning Discovery DNA Explorer Kit sold by the Discovery Channel Store that allows kids to “explore one of the newest frontiers in science—DNA mapping.”

Consumers who are uncertain about health providers' and their health insurers' ability to keep their personal health information confidential will be motivated to test at home. The market for self-testing at home is already largely saturated with home pregnancy tests; home testing for HIV is emerging. In the case of HIV/AIDS, some affluent patients have gone abroad for treatment or they self-prescribe and import medication from overseas. As more tests get commercialized and priced right, those consumers who perceive themselves at risk for particular conditions and

who highly value privacy will be key markets for home testing.

Health technology developers (including pharmaceutical manufacturers) and consumer goods companies are coming together to target consumers with innovative new products and services that involve diagnostic and monitoring applications. Where these ventures are based on sound market research and consumer segmentation, consumers will be drawn to these products and services, for example, those that allow increasingly frail elderly to live independently at home longer.

Retail players also see health as a growing consumer category that can drive sales. Supercenters, department stores, drugstores, grocery stores, and online retailers will provide opportunities for consumers to access health products and services for use at home. Indeed, a recent search on Amazon.com for a book on pharmacogenomics yielded a book and a

suggestion that we might also be interested in visiting a couple of genetic-testing services' Web sites.

PERSONAL HEALTH ECOLOGIES AND RISK PERCEPTION WILL SHAPE ADOPTION

The systems of health management resources and tools that individuals construct to manage their health—their personal health ecologies—will determine their proclivity for using diagnostic testing at home. Individuals vary in their management of health and in the tools and medication that they use in self-care versus what they turn to their doctor to provide. The limited success of full-body CT-scanning services has in fact depended on consumers who are willing to go outside the system to get more information about themselves.

Individual health and risk perception varies significantly. An individual falls on a continuum of perceived need for health management from concerned

Figure 4-2
Targeted to Homes: SpongeBob SquarePants Digital Thermometer and Discovery DNA Explorer Kit



Source: Becton, Dickinson and Company Press Release, September 19, 2003, "SpongeBob News Release." Discovery Channel Store.

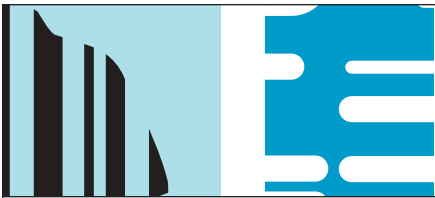


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(those who are actively concerned with managing their health) to carefree (those who seem unconcerned). The frequency, focus, and intensity of a person's use of different tools for health purposes are linked to their health status and approach to health management. Individuals will be motivated to test themselves based on their assessment of their own health risks. They will be motivated by their family health history, vague symptoms that are not sufficiently assessed or diagnosed in their minds, and even by the illnesses of those around them.



Consumerism—individuals engaging more fully in their health care experience by sharing in decision making and demanding better information, control, convenience, and customer service—has been rippling through parts of the broader health care industry for several years—and the diagnostics sector is next. A key component of consumerism is the individual managing and making choices about where to spend her health care dollars. As such, the definition often refers to services that are paid for either wholly or significantly out of pocket, but also includes increased consumer demand for reimbursed services.



5. Consumer-Driven Demand for Diagnostics

The combination of the aging of America and the growing consumer empowerment and self-agency in health care will increase the demand of diagnostic testing. A further demand driver will be the focus on screening for early disease detection. As more technologies emerge that focus on conditions for which consumers express a desire to diagnose and overcome, health care providers will assess them to see whether they could generate sufficient revenue and patient volumes to justify technology adoption. The individuals targeted for these services are often the “worried well,” those with a family history of disease but no symptoms, as well as individuals experiencing symptoms that concern them but are considered unremarkable by their physician.

At least three types of diagnostic testing services are currently available outside of the health care system and without a physician’s prescription. Diagnostic imaging at free-standing scanning centers, direct access testing (DAT), which is offered by clinical laboratories, and home testing, such as home pregnancy tests.

FULL-BODY CT SCANS

The most common type of consumer-driven diagnostic imaging test is the full-body CT scan. A small, but not insubstantial, number of both asymptomatic and symptomatic individuals have been paying out of pocket for scanning services at commercial scanning centers that are heavily marketed in many regions of the country. The number of CT scans reached 32 million in 2002, up 6 million since 1997, with a small portion of that gain coming from such elective tests.

A couple of years ago, offering CT scans to the worried well seemed like a wonderful, if controversial business idea. The pitch was usually: “Sure, you look and feel healthy. But each year, countless people succumb to the silent killers: cancer and heart disease. That’s where computed axial tomography

scanning can make a difference. A 90-second CT exam at our screening center could reveal lurking disease—before it’s too late for your doctor to do something about it. CT screening: It might just save your life.” Scans were held up as a way to empower consumers and give them more information about themselves. The concreteness of an image showing pathology had a special power for how radiologists communicated with patients. Dr. Max Rosen, a radiologist at Harvard Medical School, described this relationship with information in a recent AMA discussion on the topic:

It always struck me how powerful it was when I needed to explain a procedure to a patient. I find myself taking the patient into the back room and sitting them down either in front of film or now in front of our picture archiving system and showing them their images. It opened up a whole [new] world to the patients, patients were really riveted by their images, and it made the information that I was trying to convey much more meaningful and much more real to the patients. I was able to get the information across in a shorter period of time.⁹

On the other hand, questions were raised about whether consumer-driven scans were ethical since there would be a large number of false positive results and it was very difficult to educate consumers about the risk–benefit tradeoff involved. Many doctors and medical associations balked at the trend. The FDA, the American Cancer Society, and the American College of Radiology recommend against the exams for patients without symptoms. Many physicians say self-referred screenings aren’t worth the money, especially because most insurance companies won’t pay for screenings on a preventive basis.

So many centers began offering the scans it triggered brutal price wars. The most expensive scans originally cost approximately \$1,500 but are now

available for as little as \$500. In addition, a smaller customer base than originally expected, a tight economy, the infrequency of insurance reimbursement, and rare repeat business have also forced many centers to close. This year, AmeriScan, one of the largest scanning companies, shrunk from 12 markets to two in wealthy communities in Arizona and California.¹⁰

The scanning centers themselves fall under few regulatory guidelines. The FDA has approved the use of CT scanners for diagnostic use, but not for screening purposes. That means companies are using the machines “off label.” As long as they don’t include the names of specific machines in advertising, even the most erroneous claims are hard to stop. Still, proponents contend CT screens are going through the same struggles and criticism other screening technologies had to endure before receiving broader approval.¹¹

Who’s Getting Scanned?

The people most likely to use these out-of-pocket services are those who want more than what they currently have access to in the traditional health care system. Some are uninsured or self-employed and either can’t get access to the tests they want or find the cost is actually cheaper than going through the health care system. Some are dissatisfied with their doctor’s assessment of their situation or don’t feel their doctor is listening to them. Others see themselves as perfectly healthy but want to be tested as a baseline for future illness they expect to get or because they’ve hit a major milestone in their life, such as retirement. Finally, there’s a group of individuals who are the “worried well” those who are concerned and curious about every ache.

ITF’s 2003 Household Survey asked individuals about their health behaviors related to diagnostic testing. Not surprisingly, seriously and chronically ill

individuals report taking up to three times as many diagnostic tests as do healthy respondents within the last five years. Individuals who have gotten a full-body CT scan share some characteristics and resemble engaged health care consumers. They are more likely to be female, unemployed or retired, and have a chronic illness. They are twice as likely to spend two hours or more every week dealing with their health as those who haven’t had a scan. They are more likely to go online to get information about health and also more likely to get information about their health from all the sources in the survey. They visit the doctor more often and use more over-the-counter products.

From focus groups with individuals who had had scans, we learned that there are many reasons why individuals choose to get scanned outside of traditional health care (see text box, “Why People Choose Full-Body Scans” on page 38). Beyond family history, symptoms, and feeling at higher risk because of past behaviors, individuals talked about planning for the future, assuring the security of their family, and the value of information for information’s sake. The latter three reasons would likely fall outside of the definition of “medically necessary” but consumer utility for a test doesn’t necessarily equate with clinical utility. Consumers plan to use the information from their tests in making financial and long-term decisions, not just treatment decisions. Most wanted the sense of security, whether false or not, that a “clean bill of health” would give them. Understanding this difference in utility and talking with consumers about their health risks will become much more important in the context of genetic testing where probabilistic risks are at play.

5. Consumer-Driven Demand for Diagnostics

WHY PEOPLE CHOOSE FULL-BODY SCANS

Family History

I've outlived my father now by a year. He died of cancer when he was 43, and at the time I thought that that was a ripe old age. Now I'm like, "Oh my gosh, I'm just beginning to live."

—44 year-old woman

My motivation was the aging process. None of the men in my family made it out of their 60s.

—62 year-old man

[My mom] got a raw deal because her husband died of cancer when he was 43, her only brother died of cancer when he was 56, and he was 12 years older than she. ... Her mother died when my mother was 20, she died in a car accident. And I was thinking, "My gosh, I can't get cancer, because then my mother would lose a daughter to cancer, I can't do this to my mother." So I have to be very proactive. I did the full body scan.

—45 year-old woman

Symptoms

I went and got a heart scan, and I would have gotten a full-body scan if it hadn't been so expensive. I paid for it out of pocket. And I did so because I was having some intermittent pains in my chest and some numbing in my arm. ... I just wanted to know ... if the scan could tell me something about these pains I was having.

—57 year-old woman

Baseline Measurement

It [a heart scan] seemed like a good thing to have as a baseline. ... I know heart disease runs in my family, I know I'm an excellent candidate for it, and since I had no symptoms at the time, I thought this would be like a baseline thing to have. ... I thought it would be helpful to know, when I develop the inevitable heart problems that I was likely to develop, to know where I was at a time when I felt pretty healthy.

—63 year-old woman



My Risky Lifestyle

Oprah had it on TV. She had one and I started thinking, I do all the bad things, I eat, I don't exercise. I'm doing all the wrong things. Maybe I should go see if I'm paying the price here.

—56 year-old woman

Value of the Information

I got a little graph. I think it was two pages or something. And you breathe a sigh of relief and you go, "That scan was worth the \$1,000 for peace of mind."

—56 year-old woman

I just think information is valuable. If you have it, even if you can't do anything about it, there are some things you can do and you just have to be able to be strong enough to prepare yourself mentally to handle things. There are things you can do both mentally and diet-wise or whatever to prolong it. You're probably not going to prevent it, but prolong it. And I think it's good for your ancestors to know, or your kids, grandkids, and so forth.

—67 year-old man

Planning for the Future

If I felt I was in danger of Alzheimer's, which I don't, I would make sure that every dot was dotted and every "T" was crossed in my power of medical attorney, in my stockpiling of self-deliverance pills, in how and when I wanted to be treated when I was incapacitated, all that sort of thing. Because I feel very strongly that I would not want to live under certain circumstances.

—63 year-old woman



5. Consumer-Driven Demand for Diagnostics

DIRECT ACCESS TESTING

Another form of consumer-driven testing is direct access testing (DAT) offered by a few clinical laboratories. Until recently most states prohibited labs from accepting consumer requisitions without a physician's prescription. However, federal regulations don't restrict it, and state regulations vary widely and are changing fast. A few years ago, Quest Diagnostics, one of the largest lab companies, began to offer a service that allows consumers to order some of the most basic tests at a Quest patient service center or in retail pharmacies (see Figure 5–1). The service, called QuesTest, allows consumers to obtain results through several means, including Quest's Web site. Quest is banking on the notion that consumers are willing to pay out of pocket to obtain accurate, timely information about their health. Quest has been quiet about the success of the model but is expanding the service.

A number of drivers of DAT are resulting in growing interest across the lab sector; Quest's venture, the full-body CT scan industry, and the high-profile nature of genetic testing. It is important that labs offering DAT select an appropriate test menu, collect payment up front, keep reports simple, and not diagnose or offer prognostic information. Most ventures are not offering assays for common infectious diseases, genetic testing, tests requiring extensive interpretation by clinicians, or tumor markers. Thus far, they have also not been following up to determine what consumers are doing with the test results.¹²

THE FUTURE OF CONSUMER-DRIVEN TESTING

The problems with consumer-driven testing lie in medicine's difficulties in defining normality, the devil of "false positives," and our limited understanding of the natural history of disease. We generally define "normal" as within two standard

Figure 5–1
QuesTest Lets Consumers Order Their Own Tests



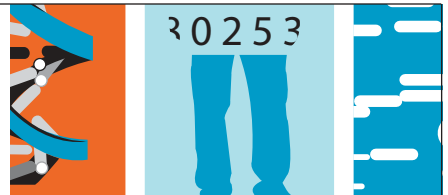
Source: Quest Diagnostics Inc.

deviations of the mean. So in a set of measurements from a normal population only 5 percent are generally classed as “abnormal.” However, widespread use of full-body scans will produce hundreds of measurements, and genetic testing will generate thousands in the future. With so many measurements, few people will be “normal” in all of them. Then the question remains, which of your abnormalities signify serious disease? There is also the possibility that identifying abnormalities in all of us will result in a reconceptualization of health. In the future, we may all be asymptotically ill waiting for our known problems to manifest and trying to prevent them from happening in the meantime.

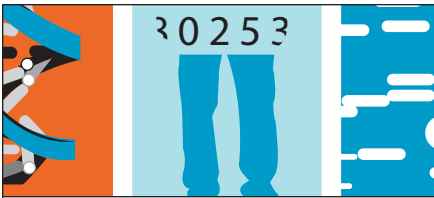
The controversy around consumer-driven testing will continue as long as there is a market for it and no regulation against it. A study examining the appropriateness of direct-to-consumer advertising of genetic tests described three factors that limit the value and appropriateness of ads: complex information, complicated social context surrounding genetics, and a lack of consensus about the clinical utility of some tests.¹³ Specifically, the ads overstate the value of genetic testing for consumers’ clinical care, provide misinformation about genetics, exaggerate consumers’ risks, endorse a deterministic relationship between genes and disease, and reinforce associations between diseases and ethnic groups.

As we learn more about the molecular and genetic nature of diseases, we’ll move from the traditional set of norms based on the 70-kg, white male to norms for subpopulations defined by genetic commonalities. The media and their coverage of genetic innovations continues to drive public calls for premature testing applications. With announcements about innovations in genomic medicine, the public has become excited about the prospect of knowing more about themselves, particularly their future risk of disease. Health professionals and facilities will be challenged to respond to the leading edge of impa-

tient and informed consumers, who demand tests and therapies that are not really ready for prime time. These consumers will also continue to demand access to and reimbursement for investigational genetic therapies, which will necessitate policy discussions among payers and their technology assessment committees.



In the future, for sick individuals, we will have disease assessment, treatment tailoring, monitoring, and targeted follow-ups. For those who aren't sick, we'll increasingly screen for preclinical disease and predisposition. Risk-modification strategies will involve pharmacogenomics to stratify the population into subclasses that help identify their ability to respond to various health-management techniques. These health-management strategies will prolong life and improve the quality of life but not without cost. The individual must actively participate as an informed consumer in health for the rest of his life, taking on the risks and responsibilities of that expanded knowledge. For those who want comprehensive health management, that is the trade off that they will have to make.



6. In the Future

THE TECHNOLOGY'S GETTING BETTER AND GOING MOLECULAR

Advances in diagnostic technology will continue along their current path of increasing precision in all testing and the gradual influx of more molecular testing (that is, pharmacogenomic testing) for monitoring and therapeutic purposes. The result will be more testing all along the care path and a desire to do more testing when it's at hand, easy to use, and (eventually) cheap. Molecularly targeted testing will remain complex and difficult to implement except where biomarkers have been identified and their role in the disease process validated. The overall outcome will be more precise and immediate results and quicker turnaround for many tests that take place at the point of care, in many cases earlier diagnosis and intervention in illness with better outcomes.

Measurement acquisition will be increasingly decentralized and their interpretation centralized. The digitization of all diagnostic information will facilitate a faster turnaround and create significant new work in data management. Each new diagnostic test enters the market with a period of significant utilization variation while standards of care and clinical indications are established. The next five years will see the establishment of standards for genetic technology and testing, the addition of computer-based analysis aids to many tests, and significant debate about which types of diagnostic tests are conducted and reimbursed and who administers and interprets them.

COST DRIVERS WILL CONTINUE TO DOMINATE

Institute for the Future research has long shown that new technologies adopted in health care are additive, not substitutive. This trend will continue as new diagnostic technologies make their debuts over the next decade. However, the next several years will be a time of very tight financial resources and health budgets; new technologies will be intensively scrutinized for their cost-effectiveness.

One universal truth holds true across the four delivery sites: reimbursement will be the prime determinant of diffusion of new diagnostic technologies. This is not a new dimension in forecasting demand in the U.S. health care market. What is new is that in the immediate future, a new payer entity will play a larger role: the consumer. And the consumer's demand for a growing array of consumer-facing technologies will become a key element of the reimbursement equation. Increasingly, the subject whose blood, bones, and DNA are being analyzed will also contribute a large chunk of the payment for that clinical transaction and determine the testing location. For example, if a patient demands a test, which is reimbursed in the hospital setting but requires a significant co-payment in the physician's office, that consumer will inevitably vote with her pocketbook and be tested in the hospital.

Like reimbursement, another clear signal in the otherwise murky crystal ball is that technology will continue to be a cost driver in health care. Ten years ago, Joseph Newhouse, one of the fathers of health economics, pointed out that technology is *the major cost driver* and accounts for over half of the increase in medical expenditures over the last 50 years. Newhouse calculated this 50-percent figure well before the advent of the Internet's reach in health care, the proliferation of PET scanners, and the mass merchandising of pharmaceutical products via direct-to-consumer advertising on television.

CONSUMERS HAVE THE LAST WORD: TEST ME, PLEASE?

Consumer self-care and demand for information will drive all forms of diagnostic testing. Individuals value information for many reasons, including planning for the future, and even information for information's sake. Clinical utility and social utility of diagnostic information do not always match up, as clinically appropriate screening would primarily be for those in a subpopulation that are identified as "at risk." Direct-to-consumer pharmaceutical advertising has been the model for "educating" individuals about their potential health risks. This, in turn, has opened the door for controversial commercial services such as full-body CT scans and direct-access testing, which primarily test those who have self-selected as having some risk. As consumers sort out for themselves what they want to test for and as more lab tests and eventually genetic tests are made available, the medical community and payers will continue to struggle with the ethics of increased demand for screening and diagnostic testing services.



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