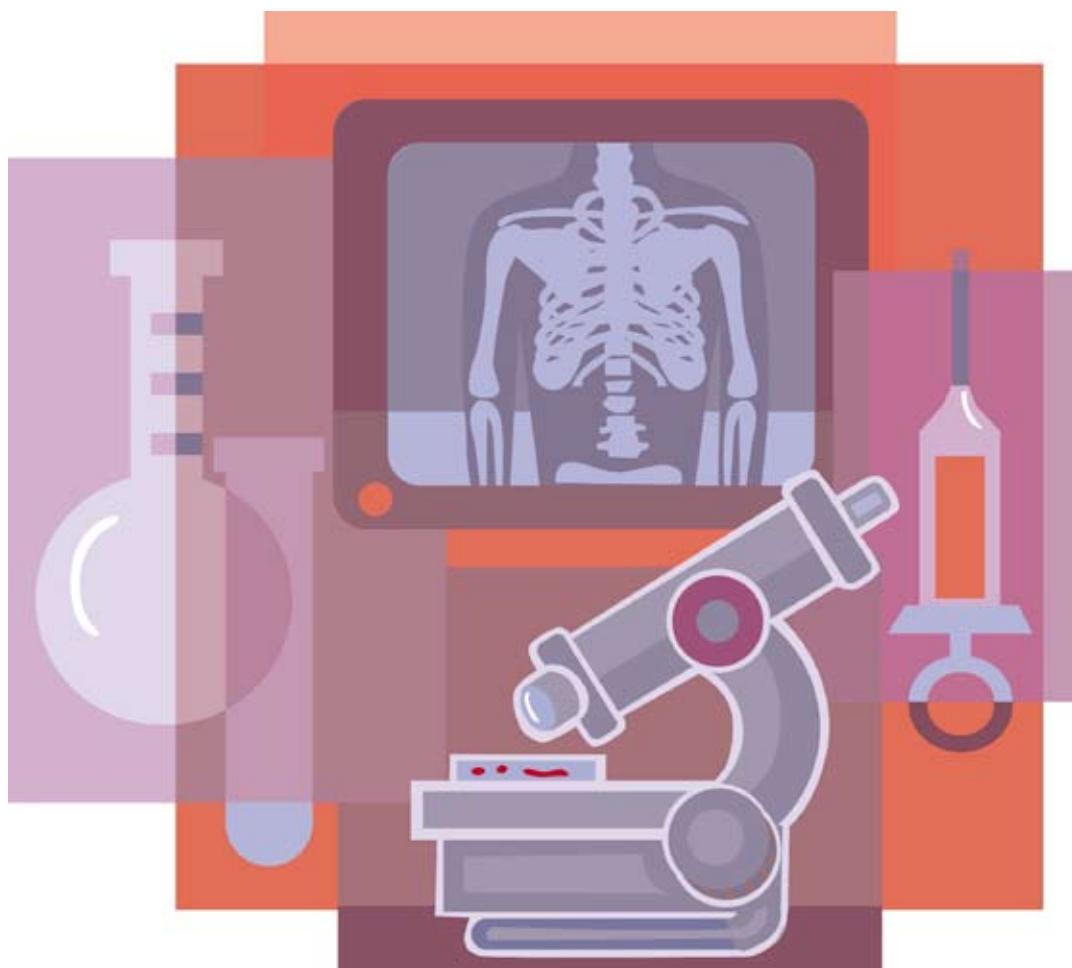




CALIFORNIA
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Under the Microscope: Trends in Laboratory Medicine

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Under the Microscope: Trends in Laboratory Medicine

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by
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The Lewin Group, a national consulting firm based in Falls Church, VA, specializes in a wide range of health and human services. It provides analyses and strategic counsel to many public agencies, nonprofit organizations, industry associations, and private companies.

About the Foundation

The **California HealthCare Foundation** is an independent philanthropy committed to improving the way health care is delivered and financed in California. By promoting innovations in care and broader access to information, our goal is to ensure that all Californians can get the care they need, when they need it, at a price they can afford. For more information, visit www.chcf.org.

Contents

2	I. Executive Summary
3	II. Introduction
4	III. Market Trends Revenues and Sectors Key Areas of Market Growth Future Demand for Testing
8	IV. Vendors Hospital Labs Physician Office Labs Independent Commercial Labs
11	V. Market Influences Economic Factors Regulatory Factors Workforce Factors
17	VI. Health Information Technologies and Related Obstacles Web-Based Technologies Other Electronic Tools Data-Sharing Challenges
23	VII. Demonstrating the Value of Laboratory Medicine Performance Measurement Outcomes Measurement
27	VIII. Conclusion
29	Appendices: A: Waived and Non-Waived Tests B: Lab Data Standards Initiatives C: Performance Measurement Initiatives
32	Endnotes

I. Executive Summary

This report provides an overview of today's laboratory medicine sector and the economic, regulatory, workplace, technological, and other factors that are shaping it.

LABORATORY MEDICINE PLAYS AN INTEGRAL ROLE IN health care, which is handicapped by overuse, underuse, and misuse of services; poor communication and coordination; and inefficiency. Labs can generate valuable data to help correct these problems by virtue of numerous scientific and technological breakthroughs that enable early detection of disease and better management of medical conditions.

This report provides an overview of today's laboratory medicine sector and the economic, regulatory, workplace, technological, and other factors that are shaping it. It discusses issues including an expanding, consolidating, and highly competitive market for diagnostic tests, especially new genetic and molecular assays; an inconsistent array of reimbursement policies; challenges related to testing standards, the qualifications and availability of lab personnel, and regulation of cutting-edge tests; and how technological advances—electronic health records, Web-based applications, and laboratory information systems, among others—along with cost-effectiveness analyses and comparative effectiveness research are altering the testing landscape. Laboratory medicine will play an ever greater role in repairing the fractured health care system as stakeholders increasingly demand scientific evidence for clinical decision making and strategies to address care quality, outcomes, and cost.

II. Introduction

An estimated 70 percent of medical decisions regarding prevention, diagnosis, and treatment involve lab tests.

FROM CHOLESTEROL TESTS TO CANCER SCREENING AND complex genetic tests, laboratory medicine is a critical component of patient care, self-care, public health, and biomedical research. An estimated 70 percent of medical decisions regarding prevention, diagnosis, and treatment involve lab tests.¹ About 62 percent of patients expect to receive such a test or an order for one during physician office visits, nearly equal to the 63 percent who expect to receive a drug prescription.² Patients may even view lab tests as evidence of sound medical treatment or acknowledgment that their concerns have been heard.³

In response to increasing demand, the number of labs has expanded greatly over the past several decades. There are now nearly 210,000 certified clinical labs in the United States, including independent commercial facilities and labs in hospitals, physician offices, long term care facilities, and other settings.⁴ A key point of leverage for labs is their ability to make data electronically available in real time at the point of care, especially as health care providers adopt electronic health records. Among the technologies now playing an integral role in lab medicine are electronic messaging, Web portals, computerized physician order entry, and software for clinical decision support.

This report provides an overview of current and anticipated trends in laboratory medicine. It looks at vendors' market share; the growth in particular types of tests; the economic, regulatory, and workforce factors that influence the highly competitive lab market; health information technologies that are transforming the market; and the increasing interest in using lab data as a key indicator of health outcomes, the quality and effectiveness of patient care, and provider performance. Understanding these trends and the related opportunities as well as hurdles may foster better health policies and strategies for improving health care access, delivery, and outcomes.

III. Market Trends

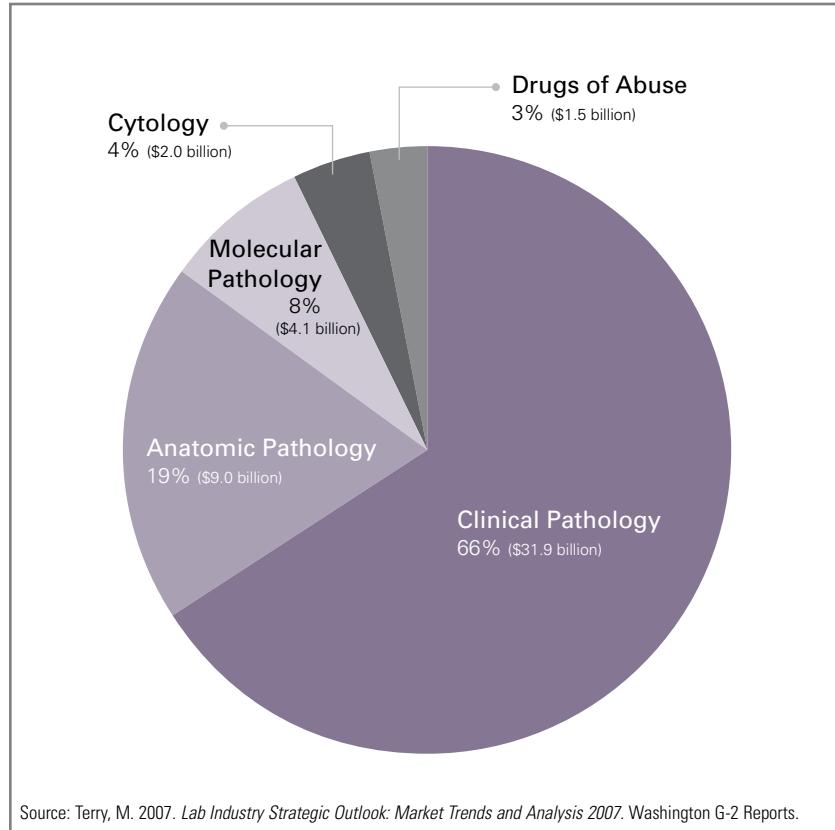
Between 2003 and 2006, spending growth on laboratory services averaged 7 percent annually. About 6.8 billion tests were performed in 2008.

Revenues and Sectors

Over the past decade, the U.S. market for laboratory testing has grown substantially in revenue, spending, and test volume. Revenues were \$48.5 billion in 2006 and an estimated \$51.7 billion in 2007, and have increased by more than 40 percent since 1998 (not adjusted for inflation).⁵ Between 2003 and 2006, spending growth on laboratory services averaged 7 percent annually.⁶ About 6.8 billion tests were performed in 2008.⁷

The largest sector in lab medicine in terms of test volume and revenue is clinical pathology, followed by anatomic pathology and molecular pathology/esoteric testing (Figure 1). Clinical pathology seeks to diagnose disease by analyzing bodily fluids such as blood and urine. A common clinical pathology test is a complete blood count.

Figure 1. Major Testing Segments in the Laboratory Industry, 2006



Anatomic pathology seeks diagnoses based on gross, microscopic, and molecular examination of organs, tissues, and whole bodies. Pap smears are a common test in this sector. Molecular pathology, a crossover of clinical and anatomic pathology, examines protein molecules, genes, and other biomarkers in organs, tissues, and bodily fluids.⁸ Tests to detect genes for familial breast cancer are an example of molecular pathology analysis.

Key Areas of Market Growth

Although clinical pathology still accounts for the bulk of test volume and revenue, five categories of tests in particular are changing the lab medicine landscape and its role in health care.

Molecular Diagnostics

The greatest annual increase in both test volume and revenue is predominantly occurring in pharmacogenomics (184 percent) and oncology testing (68 percent), followed by genetic testing (about 11 percent) and infectious disease testing (nearly 4 percent).⁹ Rapid advances in testing associated with pharmacogenetics, genetics, and biomarkers are altering the profile of molecular diagnostics.

Higher reimbursement for more expensive tests spurs investment in their development. The average charge for a molecular test is about \$177, compared with about \$30 for the non-molecular variety.¹⁰ Also fueling growth in molecular diagnostics are the higher profit margins for advanced reagents and testing instruments; increasing clinician acceptance and use of this approach instead of, or in addition to, traditional clinical pathology analyses; and greater demand for medical care tailored to individuals, which relies more on molecular testing.¹¹ According to one projection, U.S. companies will garner half of an estimated \$92.1 billion in worldwide molecular

diagnostics revenue by 2016. Pharmacogenomics will generate the most revenue in this category (nearly \$70 billion), followed by infectious disease tests (more than \$12 billion), oncology tests (nearly \$10 billion), and genetic tests (more than \$5 billion).¹²

Passage of the federal Genetic Information Nondiscrimination Act (GINA) in May 2008 will very likely boost the genetic-test market.¹³ GINA, which protects the privacy of personal genetic information and prohibits related discrimination by employers and health insurers, seeks to instill confidence in consumers and practitioners so they will take greater advantage of these predictive tests for illnesses such as cardiac disease, cancer, diabetes, and hypertension. It also seeks to foster greater participation in clinical trials of genetic and molecular testing.

Cytologic Testing

In this subspecialty of anatomic pathology, experts analyze cells to diagnose disease. Cytologic testing is the gold standard for detecting many diseases, including common cancers such as uterine and cervical cancers, leukemia, and lymphomas.¹⁴ A major contributor to its growth has been the nearly complete transition from traditional Pap smears to liquid-based, thin-layer slide preparation testing methods for cervical cancer screening.¹⁵ Pap smears involve fixing specimen cells on a glass slide with a spray before sending the slide to a lab for analysis. In the thin-layer approach, the specimen is mixed into a vial of liquid preservative and sent to the lab, which prepares the slide. This enables cleaner, more uniform analyses.¹⁶

Reimbursements for thin-layer Pap smear tests are about \$10 higher than reimbursements for the older tests. Thanks in part to the newer method, revenue for gynecology-related cytologic testing more

than doubled between 1998 and 2005.¹⁷ The market will probably expand as a result of innovations in automated testing and incorporation of digital imaging.

Point-of-Care Testing

Significant market growth is also occurring in point-of-care testing (POCT)—otherwise known as bedside, near-patient, decentralized, or alternative site testing—that takes place at or near the site of primary, secondary, or tertiary care.¹⁸ Given the close proximity of testing, results are available sooner, enabling more efficient clinical decisions in efforts to improve patient and economic outcomes.¹⁹ POCT is feasible because of advances in small and portable testing technologies for minimally invasive patient assessment.²⁰ For example, some POCT devices use infrared sensors to measure glucose and other substances directly through the skin.²¹

Direct Access Testing

In direct access testing (DAT), consumers order a laboratory test directly from a laboratory without the involvement of a health care provider. Fueling interest in DAT are greater consumer access to medical information, direct-to-consumer advertising, and an emphasis on consumer empowerment.

Although this type of testing is convenient for consumers, it raises concerns that they may misinterpret their lab results.²² Consumer demand for DAT, especially genetic testing, is creating incentives for laboratories to provide interpretive services in lieu of clinicians. In addition, patients can easily access test results via the Internet. Demand for DAT will probably increase as scientists learn more about the genetic determinants of disease.²³

Home Testing

Technological advances have made a growing number of tests—for blood glucose and cholesterol levels, pregnancy, and other conditions—more available over the counter.²⁴ Such tests are increasingly user-friendly and accurate, and can track results over time.²⁵

Revenue in the home testing market nearly doubled between 1994 and 2000, from \$1.19 billion to \$2.34 billion. The Food and Drug Administration (FDA) has approved more than 500 over-the-counter home tests.²⁶ In coming years, the scope of these tests will expand to include earlier screening for more chronic diseases and other conditions. Also anticipated is greater computer communication of results to providers, enabling them to read and interpret test results remotely, track patient self-management, and intervene as appropriate.

Future Demand for Testing

The main factors that will continue to increase demand for lab testing are:

- The United States leads the world in total and per-capita health care spending, yet quality, patient safety, and health outcomes fall short of this extraordinary investment.²⁷ Many quality shortfalls arise from the overuse, underuse, and misuse of services; poor communication; and systemic inefficiency and failures. Efforts to improve quality are drawing heavily on appropriate use of lab testing for early detection of disease and patient management that is safer and more effective, efficient, and cost-effective;
- An aging population and corresponding increase in the prevalence of chronic diseases are accelerating the use of lab tests to screen, diagnose, and manage patients.²⁸ The number of Medicare enrollees—about 44 million in

2007—is projected to increase 1.6 percent annually and reach 89 million by 2050.²⁹ A recent study found that 33 to 67 percent of Medicare beneficiaries have three or more chronic conditions.³⁰ Population growth also contributes to the increasing volume of lab tests;

- The Human Genome Project and other scientific advances are enabling the development of many new genetic tests and molecular diagnostics for a variety of diseases.³¹ In 2007, there were genetic tests for more than 1,400 conditions caused by inherited or spontaneous changes in DNA, such as tests for the breast cancer genes (BRCA1 and BRCA2) associated with a predisposition to breast and ovarian cancer.³² Identification of the genes involved in a patient's response to drug therapy through pharmacogenomic testing has helped reduce adverse drug reactions;
- Miniaturization and related technological innovations have led to the development of handheld devices for point-of-care testing by providers and self-testing devices for consumers to help them manage their chronic diseases and medications, such as insulin and warfarin therapy. Other advances have improved laboratory instrumentation that improves the high-volume efficiency of common blood and urine tests;³³
- An accumulation of evidence demonstrating links between certain biomarkers and patient outcomes is prompting increased emphasis on lab tests for these biomarkers in clinical practice guidelines,³⁴ quality indicators,³⁵ and related performance measurement. For example, seven of the eight clinical conditions included in the National Health Care Quality Report of the Agency for Healthcare Research and Quality relied on lab test results as indicators; and
- The increasing amount of health information, media attention to health care issues, and direct-to-consumer advertising of new tests have enhanced consumer awareness of and interest in lab testing.³⁶ In metropolitan areas, providers ordered more tests when a genetic test for breast and ovarian cancer was directly marketed to consumers, according to the Centers for Disease Control and Prevention.³⁷

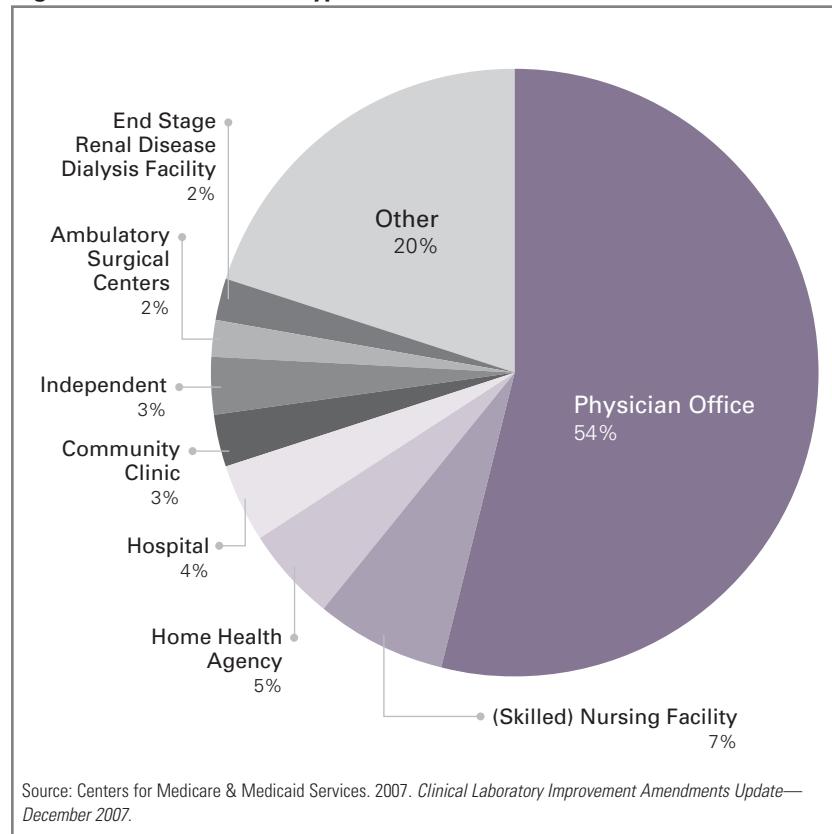
IV. Vendors

Lab test sites and the entities that perform tests are expanding and diversifying along with dramatic changes in the types of tests.

HOSPITALS, PHYSICIAN OFFICES, INDEPENDENT LABS operated by nonprofit entities or for-profit corporations, public health departments, nursing homes, and other facilities all do lab testing (Figure 2). Lab test sites and the entities that perform tests are expanding and diversifying along with dramatic changes in the types of tests. This diversification has improved consumer access to lab services and has enabled health care providers to increase their scope of services, competitiveness, and revenue.

All testing labs must register with the Centers for Medicare & Medicaid Services, obtain certification from the Food and Drug Administration for the level of testing they intend to conduct, and comply with requirements under the Clinical Laboratory Improvement Amendments of 1988.

Figure 2. Most Common Types of Labs, 2007



The following section summarizes the major lab testing sectors. It also discusses the effect of recent merger and acquisition activity in this market, and the competitive advantages and disadvantages of several primary types of labs.

Hospital Labs

Although hospital-based labs make up only 4.4 percent of the entire market, in 2006 they performed the largest share of testing (55 percent) in terms of volume and revenue. Their estimated revenue for 2007 was \$28.4 billion, an increase of more than 6 percent from the previous year. Among the top 10 hospitals with the highest testing volume, Baystate Medical Center in Springfield, Massachusetts, by far conducted the most tests in 2007 (38.7 million); volume at the other nine labs around the country ranged from 11.1 million to 16.9 million tests.³⁸

The core business of hospital labs is serving their inpatient and outpatient populations. But many also reach out as reference labs to provide testing services to other facilities, including hospitals, community clinics, and physician offices, which has boosted their revenue and enabled them to compete more aggressively with independent labs.³⁹ Reference testing accounted for 29 percent of hospital lab testing volume in 2005. Nearly half of hospital reference labs reported that they were holding on to market share against their two main private-sector competitors, Quest Diagnostics and Laboratory Corporation of America. About 40 percent indicated they were gaining market share and 15 percent reported losing market share.⁴⁰

Physician Office Labs

The greatest proportion of testing labs—nearly 54 percent—is in physician offices. However, they conduct just 8 percent of all tests and garner

only 5 percent of market revenue, which fell from \$2.8 billion in 2003 to \$2.5 billion in 2006.⁴¹ Nearly all testing at physician office labs involves “waived tests”—assays unlikely to result in errors, given their simplicity and accuracy—and “provider performed microscopy.”⁴² (See Appendix A for more details about these and “non-waived” classifications.) The most common type of test these labs conduct is dipstick/tablet urinalysis, followed by fecal occult blood, urine pregnancy, rapid strep, vaginal smear/wet mount, and others.⁴³ Testing is typically limited to a few types of specimens.⁴⁴ One advantage of physician office labs is that clinicians have immediate access to results.⁴⁵

Independent Commercial Labs

Three publicly traded, independent laboratories dominate the U.S. market: Quest Diagnostics, Laboratory Corporation of America, and Genzyme Genetics.⁴⁶ In 2007, their respective annual revenues were \$6.71 billion (up from \$6.27 billion in 2006), \$4.07 billion (up from \$3.59 billion), and \$3.81 billion (up from \$3.19 billion).⁴⁷ Two private, independent vendors—ARUP Laboratories and Mayo Medical Laboratories—are the next largest in terms of revenue.⁴⁸ In contrast to these top five, the great majority of labs have annual revenue of less than \$20 million.⁴⁹

There has been considerable merger and acquisition activity in the lab testing market in recent years, led in particular by Quest and LabCorp. All but one of the top 10 independent commercial labs in 2001 have since merged with one of these two companies.⁵⁰ Acquisitions are motivated by labs’ desire to increase market share and gain testing capabilities in specific therapeutic areas. For example, by purchasing an immunoanalytical lab called Tandem Labs in 2007, LabCorp sought to enhance its personalized care capabilities and facilitate its

partnerships with pharmaceutical companies to develop companion diagnostics.⁵¹ Quest's 2007 purchase of AmeriPath, a major anatomic pathology lab, expanded its share of the cancer diagnostics market.⁵² This approximately \$2 billion acquisition was the largest to date⁵³ and far exceeded the previous high of \$918 million that Quest paid for Unilab in 2003, the leading independent lab in California (see box).⁵⁴

Acquisition prices have been increasing in recent years as a result of greater competition among financially healthy companies.⁵⁵ Another trend is the purchase of labs by private equity companies, which often can pay higher average price multiples⁵⁶ than publicly traded, independent labs.⁵⁷

Many large independent labs have several competitive advantages over small, regional labs and those in hospitals. These advantages include large, national managed care contracts, lower supply costs, more complex testing capabilities, more efficient billing and collection management, and greater resources to invest in Web-based applications.⁵⁸ On the other hand, smaller labs can provide test results more quickly and have greater flexibility in terms of scheduling specimen pickups, as they typically serve smaller regions. In addition, they may be more accessible for communications with health care providers and may emphasize customer service.

Some small start-ups are making inroads into the lab testing market. Many offer molecular diagnostic tests in geographic regions where larger independent labs are not as dominant and patient demand is increasing.⁵⁹ Despite competition from hospital outreach labs and the high cost of adopting new technologies, some of these start-ups have successfully created niche markets and formed partnerships with local, small to mid-size hospitals.

Independent and Hospital Outreach Labs in California

Nationally, California has the largest market for independent and hospital outreach labs. In 2007, they performed an estimated 118.7 million tests that generated \$1.9 billion in revenue.

Quest and LabCorp dominate the California market. Five Quest labs and two LabCorp labs rank among the 12 highest-volume labs in the state. Spectra Laboratories also has a significant presence in California.

Texas and New York are the next-largest state markets. In 2007, independent and hospital outreach labs in Texas performed 73.4 million tests (\$1.2 billion in revenue) and those in New York performed 67.5 million tests (\$1.1 billion in revenue).

Source: Terry, M., ed. 2007. *Laboratory Market Leaders Report 2008*. Washington G-2 Reports.

V. Market Influences

Over the past few decades, labs have faced cost-cutting measures and other efforts to manage the use of and payment for their services.

ECONOMIC, REGULATORY, AND WORKFORCE FACTORS are shaping the dynamics of the lab sector. They affect labs' ability to compete, manage risk in light of regulatory safeguards, and meet future workforce demands.

Economic Factors

All sectors of the health care system are under pressure to cut costs, which places a greater financial burden on employers, patients, and providers.⁶⁰ Rising costs make health insurance less affordable and contribute to the increasing number of the uninsured and underinsured. Public and private payers are seeking ways to limit their expenditures, often by restraining or lowering payment rates for health care services and by imposing greater cost sharing on patients.

Over the past few decades, labs also have faced cost-cutting measures and other efforts to manage the use of and payment for their services.⁶¹ Some of these actions yield competitive advantages for certain laboratories—for example, negotiated national contracts between health plans and labs. Other measures, such as proposed competitive bidding on Medicare reimbursement rates, could constrain the entire lab sector.

Managed Care Contracts

The ability of major independent labs to negotiate substantial contracts with managed care plans is a significant competitive advantage because it guarantees a larger volume of tests. Under an exclusive contract, a lab is designated as the sole provider of testing services for patients insured by the health plan and receives a flat reimbursement rate. Some contracts apply to patients in a specific geographic area, such as a state, while others are national in scope.

Quest and LabCorp have negotiated major national contracts with the three largest private sector payers: UnitedHealthcare, Cigna, and Aetna. In 2006, these contracts generated 50 percent of Quest's total revenue and 42 percent of LabCorp's.⁶² LabCorp estimates that the first year of its exclusive contract with UnitedHealthcare boosted its revenue by 6.6 percent, or \$250 million, in 2007. Over the full course

of the 10-year contract, LabCorp expects to augment its revenue by \$3 billion.⁶³

Such arrangements can have a significant impact, particularly on independent labs that lose business when their competitors win large contracts. Indeed, within one hour of the public announcement of the LabCorp-UnitedHealthcare contract, shares in Quest fell 13 percent.⁶⁴ Quest later negotiated an exclusivity contract with Aetna, its largest payer, that accounted for 6 percent of its consolidated net revenue in 2007.⁶⁵

In the past several years, large health plans have increasingly limited their lab networks to a single national lab in order to obtain better pricing. Labs agree to contracted rates that are generally lower than typical “reasonable and customary” payment rates because there is potential for greater test volume.⁶⁶ If a health plan’s patients and providers choose to use a non-contracted lab, the lab is generally reimbursed at “reasonable and customary” rates. However, many labs report that this arrangement results in a much smaller reimbursement than the billed amount—in some cases, 50 percent or less.⁶⁷ Therefore, payer mix influences lab revenue. In 2006, fee-for-service payments to managed care organizations accounted for 38 percent of laboratory industry revenue, and Medicare payments for 15 percent.⁶⁸

Supplier Contracts

Larger national independent labs leverage their economies of scale to negotiate more favorable contracts with suppliers. The annual test volumes at Quest (about 300 million) and LabCorp (about 200 million) give these companies an advantage when they negotiate with reagent and supply vendors. They can purchase reagents for 30 percent to 50 percent less than what hospitals and other labs pay.⁶⁹

Federal Reimbursement

For labs, policies regarding payer coverage and reimbursement are the biggest challenges to market growth. The Centers for Medicare & Medicaid Services (CMS) is the nation’s largest payer, with \$570.5 billion in net outlays for all health care services in 2007.⁷⁰ Most federal payers and two-thirds of commercial payers base their reimbursement rates for lab services on those paid by Medicare; consequently, its payment policies for lab services apply to most health care beneficiaries.⁷¹

Coverage

Coverage policies govern the conditions for third-party payments, which are generally based on determinations of medical necessity and appropriateness. Restrictions on lab test coverage can have important implications for patient access and quality of care. Usually, public and private payers make coverage decisions independently of each other, primarily taking into account how a decision will affect the payer’s costs. The private sector generally provides broader coverage for preventive and screening tests than Medicare does; aside from exceptions specifically authorized by Congress, the Medicare statute does not permit payment for such tests.⁷² Private insurers are also quicker to cover new technologies as they arise.⁷³

Inconsistencies in coverage of certain laboratory tests, especially molecular and genetic tests, pertain to all payers. Medicare does not cover genetic tests unless the patient is symptomatic or the tests will identify treatment-responsive populations.⁷⁴ Aside from newborn screening, Medicaid coverage of particular genetic tests varies by state. Some private insurers deny coverage for specific types of genetic tests, including some for breast cancer.⁷⁵ The greatest variations in coverage have to do with new molecular tests for which there is limited scientific evidence.⁷⁶

Labs and payers need to collaborate more extensively to clarify the extent to which new tests meet medical necessity criteria when the tests are part of larger metabolic panels or more targeted profiles of specific biomarkers. Many health care stakeholders believe that oversight of genetic testing is inadequate and should be improved to protect patients' interests.

Payment

Methods of paying for laboratory tests vary by the type of provider venue (inpatient, outpatient, or ambulatory care) and type of test (for example, clinical or anatomic pathology). For most inpatient care, public and private payers apply prospective payment systems—such as diagnosis-related groups (DRGs), the codes Medicare uses—wherein rates are based on the patient's diagnosis. Most other federal payers and many private payers use Medicare's DRG groupings but assign their own payment rates. Some private payers use all-inclusive rates (based on bundling of multiple payment classifications) or per diem rates.

Implementation of DRGs by Medicare in the 1980s and other prospective payment systems transformed hospital labs from profit centers to cost centers. DRGs created incentives to reduce the number of tests ordered and to shift inpatient care to hospital outpatient and ambulatory care settings.⁷⁷ The greater number of patients receiving treatment from ambulatory care providers increased independent labs' business. To compete and return to profitability, hospital labs invested more in outreach services.

However, rising health care costs and efforts to control them have prompted payers over the past decade to bundle hospital outpatient services under "outpatient prospective payment systems."⁷⁸ Under Medicare, this created an administrative and financial burden for some independent labs because they

must bill hospitals directly for the technical aspect of testing and bill Medicare directly for pathologist fees.⁷⁹

Insurers pay for ambulatory care services, including lab tests, according to predetermined, fixed-fee schedules; negotiated contracts; or competitive bidding contracts.⁸⁰ The most prominent fee schedules are the Medicare Physician Fee Schedule (MPFS), which covers clinician services, including pathologist interpretive services for certain anatomic, molecular, or highly complex clinical pathology tests, and Medicare's Clinical Laboratory Fee Schedule (CLFS), which covers technical fees for lab tests. Private payers often set their own payment rates as a multiple or percentage of the MPFS and CLFS rates.

Medicare Competitive Bidding

The Centers for Medicare & Medicaid Services has sought to institute competitive bidding for lab services since the mid-1980s in hopes of generating substantial savings.

Supporters of competitive bidding argue that the current fee schedule has no relationship to actual costs for high-volume testing, given the greater efficiencies and economies of scale resulting from advances in automation and instrumentation. Opponents contend that competitive bidding probably would force many labs—particularly smaller labs that perform low-volume, highly complex, or specialty testing—to close. Outreach labs at hospitals and independent labs that provide testing services to prospective winners in the bidding process would be at greater financial risk.

Congress halted a competitive bidding demonstration project in July 2008, only two weeks after the project began. However, further efforts by CMS to implement competitive bidding in some form are likely.

Sources: Plandowski, J. December 2007. *Counterpoint: Time Is Right for Competitive Bidding Demo*. Washington G-2 Reports; Mensh, S. 2004. *Competitive Bidding Demonstration Project for Clinical Laboratory Tests*. Advanced Medical Technology Association; American Clinical Laboratory Association. February 2007. *The Medicare Competitive Bidding Demonstration Project Must Be Repealed*.

Under negotiated contracts, Medicare pays private health plans monthly for providing services to beneficiaries. In contrast, private payers may negotiate rates with employers or labs.⁸¹

Competitive bidding is a cost-containment mechanism whereby providers of a service or product submit bids to a purchaser; winners provide exclusive or other preferential services for a particular market and period of time. Bidding based on CLFS payment rates has posed the greatest challenge for labs because of federal efforts to freeze or lower the rates. Medicare uses 56 versions of this fee schedule that coincide with geographic areas and designated private insurers. Although payment rates differ among carriers, Congress established upper national limits. These limits have been reduced seven times since 1986 and three relatively small increases—2.9 percent in 1996, 2.3 percent in 1997, and 1.1 percent in 2003—have not kept pace with inflation.⁸² Because the allowable payments set in 1983 were not linked to labs' relative testing costs nor adjusted for inflation, some fees are most likely low while others may be high.⁸³ The use of multiple rate schedules has contributed to the administrative burden of all parties involved in competitive bidding.

Lower reimbursement rates for lab services covered by public payers have prompted some private payers to demand equivalent low rates.⁸⁴ Nevertheless, national independent labs have continued to raise their average price per test order and have expanded their menus of molecular diagnostic tests, which are paid by insurers at higher rates than other tests. Many labs are partly responding to the downward financial pressure by investing in automated testing technologies that enable greater testing volume, thus improving efficiency.⁸⁵ These technologies are expensive; often, only independent and hospital labs can afford them.

Regulatory Factors

CMS, the FDA, and certain states predominantly regulate labs. CMS, which is primarily responsible for overseeing clinical labs and their testing services, ensures that labs comply with requirements in the Clinical Laboratory Improvement Amendments (CLIA) of 1988—in particular, regulations governing the proficiency of lab workers, personnel qualifications and training, and the quality of lab equipment. It also inspects labs and oversees tests they develop and use in-house, some of which may not have received FDA approval. The FDA regulates manufacturer-developed, diagnostic-test products—for example, test kits and testing systems and equipment—as well as certain software for laboratory information systems. Twenty-six states have some degree of statutory oversight authority. CMS has exempted two states (New York and Washington) from CLIA, giving them complete authority to oversee labs in their jurisdictions.⁸⁶

The level of regulation depends on test complexity. Facilities that only perform relatively simple “waived” tests are not subject to many of the CLIA regulations, but they must follow manufacturer's instructions when performing them and must permit random inspections by designated authorities.⁸⁷ Technical requirements under CLIA for more difficult “non-waived” tests seek to ensure the accuracy, reliability, and timeliness of test results.⁸⁸

Labs that perform non-waived tests face several challenges, especially regarding newer genetic tests. Technological advances in testing, emerging pharmacogenomic and proteomic testing, and greater automation may change the necessary qualifications of, and practice standards for, the next generation of lab professionals. Many industry insiders believe that personnel qualifications and practice standards at genetic testing labs need to be revised and improved

in order to maintain testing quality and ensure the appropriate use of test results.⁸⁹

A related issue is appropriate regulation of genetic tests that labs develop in-house. To date, such tests have been subject only to CLIA regulations, while genetic tests developed by manufacturers have been subject to both those regulations and FDA requirements. Because the two regulatory frameworks serve different purposes and rely on different data, there are differences in the level of evidence they require (see box). Many observers contend that in-house tests regulated by CLIA do not receive sufficient oversight for several reasons:

- While CLIA requires that a test demonstrate analytical validity, such as its accuracy in analyzing a genotype, the standards of evidence are tied to inspections and set by individual labs, not CLIA. Therefore, analytical validity may vary among labs;
- Unlike FDA-regulated tests, the analytical validity of in-house tests is not established until after they are on the market;
- CLIA requirements for quality control, personnel, and the proficiency of lab workers are not

tailored to molecular, genetic, biochemical, or pharmacogenomic tests. Rather, the general requirements for non-waived tests apply; and

- Under CLIA, most genetic testing labs are not required to establish the proficiency of their analyses because the analytes used for genetic testing are not among the 83 that CLIA regulates. Consequently, these tests are subject to less-rigorous performance assessments.⁹⁰

Although the FDA has statutory authority to regulate tests that labs develop in-house, the agency has not exerted its authority due to resource constraints. Therefore, it recently developed two guidance documents for labs: one regarding in vitro diagnostic multivariate index assays and the other regarding analyte-specific reagents, the active ingredients in these tests. The documents will very likely expose more tests to greater pre-market scrutiny. The current regulatory framework may create incentives for labs to offer in-house genetic tests rather than market them as FDA-approved tests.

To address gaps in the regulatory framework that could compromise patient and public health, in 2008 the Advisory Committee on Genetics, Health, and

Lab Test Evidence Required by CLIA and the FDA

CLIA and FDA:

Analytical validity: the quality of measurement—a test's ability to measure the analyte or genotype of interest. Key components of analytical validity include accuracy, precision, reproducibility, and uncertainty.

FDA's Additional Requirements:

Clinical validity: a test's ability to detect or predict the disorder that is associated with an analyte measurement. Key components of clinical validity include clinical sensitivity and specificity, and positive and negative predictive values.

Clinical utility, or “clinical effectiveness”: the balance of risks and benefits associated with using a specific test in routine clinical practice.

Source: Secretary's Advisory Committee on Genetics, Health, and Society. April 2008. *U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services*. U.S. Department of Health & Human Services (oba.od.nih.gov/oba/SACGHS/reports/SACGHS_oversight_report.pdf).

Society at the U.S. Department of Health & Human Services recommended ways to improve requirements and collaboration among all parties.⁹¹ Although the recommendations' effect is not yet clear, greater consumer and provider demand for genetic testing probably will lead to greater demand for adequate oversight.

Workforce Factors

There is emerging evidence of a shortage of certain clinical laboratory workers, especially technologists/scientists and technicians, that in the near future could affect access to labs and the quality of services they provide.⁹² Contributing factors include the retirement of senior members of the workforce, competing career opportunities, and difficulty recruiting and retaining staff.⁹³ The growing shortage comes at a time of increasing dependence on highly complex molecular and genetic tests for diagnosis and treatment.

Vacancy rates vary among types of lab personnel. Current data do not indicate a shortage of pathologists.⁹⁴ While no data are available on vacancies among doctoral scientists, data from the American Board of Clinical Chemistry suggest that fewer people have been seeking board certification in each of the last several years.⁹⁵ The most recent survey of lab personnel vacancies, conducted in 2005, found that vacancy rates were highest before 2002 and began declining in 2003. Between 2003 and 2005, vacancy rates increased among technologists/scientists at the staff, supervisory, and managerial levels, and among technicians at the supervisory level.⁹⁶

How the workforce shortage will affect labs remains unclear. Recent efforts by laboratory education programs to recruit students—including efforts targeted to minorities and men—appear to be effective. They raise awareness of lab careers and dedicate staff and funds to recruitment.

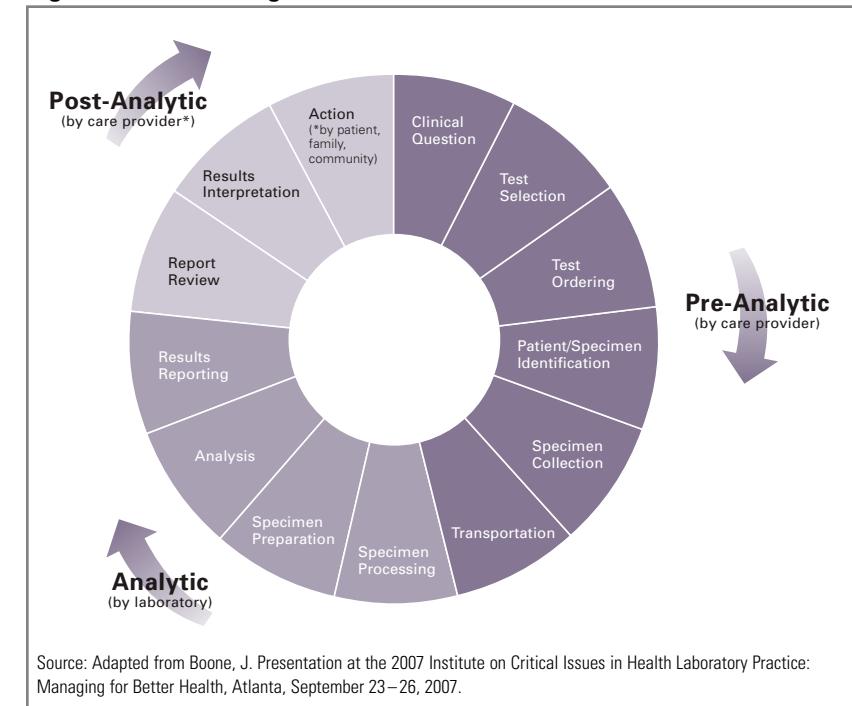
Many academic programs are developing student mentorship programs to enhance interactions with the workforce.⁹⁷

VI. Health Information Technologies and Related Obstacles

Technological advances are changing how health care providers and lab professionals communicate, provide services, educate their workforce, market themselves, and track clinical information.

LAB TESTING IS DATA-INTENSIVE. THE ENTIRE PROCESS involves a series of complex, interrelated tasks that generate important clinical data and related information (Figure 3). In each phase, data are created, organized, presented, transferred, and archived.⁹⁸ The process begins and ends with interactions between patient and clinician. Initially, the patient presents and the clinician poses a question—such as “Does he have high cholesterol?” or “How well is she managing diabetes?”—that a lab test may be able to answer. Then the clinician examines a menu of lab tests and selects the one that may best answer the question. While routine tests are relatively easy to select, the variety of new tests has made this choice more complex for health care providers in recent years. The clinician requests a test in writing or electronic form. Before the provider or lab collects a specimen, the patient’s identification is verified and specimen containers are labeled. After collection, the specimen is transported to the lab for analysis along with the related documentation.

Figure 3. Total Testing Process



At the lab and before analysis, requisition data are entered into the laboratory information system (LIS) manually or, if transferred electronically, reviewed and verified. Then the lab prepares the specimen for testing. Clinical pathology testing is highly automated and instruments increasingly are connected to the LIS to better manage the process and resulting data. Anatomic pathology testing is more labor-intensive; the pathologist must view the specimen through a microscope. The pathologist enters data about the specimen into the LIS. Molecular pathology testing involves automated preparation and analysis of the specimen as well as the pathologist's microscopic examination of molecules or genes, followed by manual entry of data into the LIS. A pathologist or technologist reviews the results. In certain instances, the specimen may be retested.

Once the test results are verified, a final report is generated and sent to the provider. Today, nearly all results are available electronically, but because many providers have not implemented electronic health records (EHRs) or other health information technologies, they cannot easily or securely exchange data with labs or other providers and organizations. Consequently, many test results are still faxed to providers—even when test values are abnormal, although accreditation and quality improvement organizations require lab professionals to call providers to relay such results. The clinician must interpret the results accurately and discuss them with the patient. Timeliness and accuracy in reporting normal and abnormal results are essential for proper clinical care.⁹⁹ Lastly, the clinician and patient decide which course of action to take.

To improve the quality and safety of patient care, providers need real-time access to lab data at the point of care. This requires better data sharing between providers and lab professionals

during test ordering and results reporting. To meet challenges posed by the growing population of patients with multiple chronic conditions, clinicians must be familiar with the larger number of tests now available. Medical education about lab testing is inadequate and the quality of “curbside consultations” among clinicians regarding tests may vary depending on the expertise of the consulting physician. Some of the new, complex tests are more difficult to interpret without help from laboratorians.¹⁰⁰ Given that many clinicians find it increasingly difficult to keep up with the demands of day-to-day practice, greater reliance on clinician-lab consultations can help reduce inappropriate use of tests and interpretation of results.

Technological advances are changing how health care providers and lab professionals communicate, provide services, educate their workforce, market themselves, and track clinical information.¹⁰¹ Web-based applications, regional health information networks, EHRs, and associated clinical applications such as computerized physician order entry and computerized decision support systems enable electronic exchange of lab data. In addition, innovations in laboratory information systems are improving data management and processing capabilities that better support health information systems and the data requirements of new, more complex molecular and genetic tests (see box on the following page).

Web-Based Technologies

Demand is growing for Web-based applications electronic messaging, portals, regional health information networks, and others that enable clinicians to order tests and receive results electronically and, in some cases, allow consumers to view test results electronically.¹⁰² In the past, most electronic data exchange occurred within integrated

Laboratory Information Systems

An LIS produces lab data for health information systems that support Web-based communication and clinical practice applications.

Library information systems are complex, comprising both administrative and clinical programs. These programs can be designed to integrate everything from managing test orders and tracking specimens to reporting results, billing, generating receipts, and managing automated instruments.* Health information applications must be able to exchange data with the LIS or an intermediary system that holds lab data, such as a clinical data repository.

LISs require regular upgrades so they can meet the data processing demands of new molecular and genetic testing technologies, and translate this complex data into useful information at the point of care.

*Source: Ward-Cook, K., C.A. Lehmann, L.D. Schoeff, L.E., et al, eds. *Clinical Diagnostic Technology: The Total Testing Process*. Volume 1: The Preanalytic Phase. Washington, D.C.: American Association for Clinical Chemistry, 2005.

health care delivery systems that used their own secure wide area networks to order lab tests and receive results. Recent gains in the efficiency of Internet-based data exchange have enabled more ubiquitous access to these functions.

Electronic Messaging

Large independent labs have led advances in Internet-based data exchange. High-volume testing generates substantial revenue that labs can use to invest in Web-based technologies.¹⁰³ Some labs invest in health information technology as part of a negotiated contract with a payer to promote the development and management of local area networks for data exchange.¹⁰⁴

Larger labs also may expand their markets in ambulatory care settings by leveraging clinician interest in using electronic health records. Given the sizable cost and complexities of implementation, it is difficult for many ambulatory care clinicians to invest in EHRs. Labs have met the demand for electronic health records and data exchange by directly providing or financing basic electronic connectivity, via the Internet or a virtual private network, for ordering tests and reporting results. These arrangements are usually limited to exchanging data with the sponsoring lab, although other health

care stakeholders are trying to mandate that all such information systems be interoperable.¹⁰⁵

To compete with Quest and LabCorp, hospital and other independent labs increasingly offer Web-based test ordering and results reporting, which means health care providers need not change their computer systems.¹⁰⁶ Most labs can now report results electronically. In addition, many new LIS vendors specialize in Web-based connectivity for ordering and reporting. Wider adoption of electronic health records by clinicians will increase Web-based exchange between clinicians and labs.¹⁰⁷

Online Portals

Providers and labs are developing Web-based portals so clinicians and patients can access test results and other health information. Recent research on inpatient, emergency room, and hospital-based clinic settings demonstrates a direct association between Web-based viewing of lab reports and improved quality of care, independent of EHR adoption. For example, viewing test results electronically reduces unnecessary repeat testing and the time to address abnormal results.¹⁰⁸ Other research has found associations between better self-care and electronic access to lab data via patient-focused Web portals, which can also provide access to medical records and enable secure patient-provider communications.¹⁰⁹

Regional Health Information Organizations

Provider and patient portals that are part of regional networks managed by regional health information organizations (RHIOs) enable designated clinicians to exchange patient data for the purpose of care coordination, communication, and research.

However, a 2007 survey of 145 RHIOs concluded that nearly one quarter were probably defunct.¹¹⁰

One highly successful regional network is the Indiana Network for Patient Care (INPC), established by the Regenstrief Institute in 1994.¹¹¹ INPC serves Indianapolis and surrounding counties. Participants include five major hospital systems, county and state public health departments, Indiana Medicaid, and RxHub, which delivers information regarding patients' use of medications.¹¹² Institutions pay a monthly fee for access to lab results, radiology reports and images, hospital admission notes and discharge summaries, operative reports, medication histories, immunization records, tumor registries, and clinicians' dictation notes.¹¹³ The National Cancer Institute developed the Shared Pathology Informatics Network so other cancer researchers would have access to INPC content.¹¹⁴

Other Electronic Tools

There is growing evidence that improving the quality of information available to clinicians through EHRs, computerized physician order entry (CPOE), and a computerized decision support system (CDSS) can reduce errors along clinical pathways.¹¹⁵

Preventable diagnostic errors include failure to use an indicated test, misinterpretation of test results, and failure to act on abnormal results.¹¹⁶ Research has demonstrated that providing laboratory test guidelines and related information on EHR screens is associated with fewer orders for overused tests and more orders for underused tests.¹¹⁷ Bidirectional exchange between CPOE tools and laboratory

information systems increases workflow accuracy and efficiency, thus reducing the turnaround time for lab tests by 25 percent. CDSSs flag abnormal test results, issue reminders for preventive tests, and minimize redundant test orders.¹¹⁸ A study in multiple Veterans Affairs ambulatory care clinics showed that computerized reminders improved resident physician compliance with standards of care.¹¹⁹ Such reminders may help improve care quality, safety, efficiency, and cost-effectiveness.¹²⁰

Although public and private health-related organizations continue to press for broad adoption of EHRs, CPOE, and CDSS, progress to date has been modest. EHR use varies among health care settings. According to a 2007 survey by the American Hospital Association, 11 percent of hospitals—most of them large, urban, academic medical centers—had fully implemented electronic health records.¹²¹ In a review of multiple EHR adoption surveys based on data through 2005, the Robert Wood Johnson Foundation reported in 2006 that the adoption rate varied: from 17 to 25 percent among physician offices, from 13 to 16 percent among solo practitioners, and from 19 to 57 percent among large physician offices.¹²² In contrast, the rate at Kaiser Permanente, the nation's largest HMO, is 79 percent in California.¹²³ About 15 percent of integrated delivery systems, 9 percent of stand-alone hospitals, and 1 percent of skilled nursing facilities and rehabilitation hospitals have implemented CPOE.¹²⁴ No data are available regarding computerized decision support systems.

Disease Registries

Disease registries are a type of clinical information system that support care for chronic diseases and other conditions tracked over time. Unlike electronic health records, they manage only information relevant to one or more diseases rather than

comprehensive information about patient problems, health history, and care. Providers can use disease registries at the point of care, between patient visits, and for population-based reporting. A growing number of registries enable patients to log in and enter data regarding their self-management of disease. Incorporating lab test results into registries can be essential for managing certain diseases. Registries also are increasingly important in population-based research—for example, in tracking the natural course of disease, treatment effectiveness, costs, and other parameters.¹²⁵

Data-Sharing Challenges

Integration of lab data into health information systems is limited, as significant technical, business, and regulatory challenges to ubiquitous data sharing have yet to be resolved.

Standards

Labs, health care providers, and technology vendors have been unable or unwilling to adopt common standards for representing and exchanging clinical data. Integrating data from various stakeholders is difficult due to the multitude of data sources associated with disparate information systems and the lack of a compelling market force to promote standardization.¹²⁶

Information exchange between laboratory information systems and EHR, CPOE, and CDSS applications and disease registries is in the nascent stages. Haphazard adoption of data standards is the chief barrier to exchange among data “trading partners,” including hospitals and clinicians who provide ambulatory care, other labs, pharmacy and radiology departments, public health entities, and insurers. These standards govern the way electronic information is represented, shared, stored, and retrieved in EHRs and other technologies.

Interoperability requires the creation, acceptance, and implementation of standards for exchange, messaging, terminology, document format, context, software, and data storage and distribution, thus ensuring that data in one part of the health system are available and meaningful across a variety of settings.¹²⁷

Most lab data standards are designed for stand-alone laboratory information systems to streamline in-house operations rather than share data with EHRs and other external technologies. And some technology vendors and health care organizations, such as hospitals, have developed proprietary standards for their own systems instead of using international organizations’ publicly available standards. In these instances, data sharing is limited to systems that are similar or produced by the same vendor.¹²⁸ Exchange typically requires special software (“middleware”) that translates the two different computer languages or requires other technical modifications, which can increase the challenges and costs related to data sharing.

Several major public and private initiatives (Appendix B) are under way to facilitate the data sharing necessary to improve test ordering, results reporting, and other aspects of clinical decision making that may involve lab data, such as the selection and monitoring of therapeutic drugs.¹²⁹

However, there has been little follow-up to press for implementation of data standards for data exchange between labs and EHRs or disease registries. Several laboratory information system and electronic health record vendors have resisted or been slow to implement the appropriate modifications because:

- The lab market is fragmented among different types of labs that target different clients; developing uniform standards for all of them is a time- and resource-consuming challenge. In California, for example, more than 100 labs do

outpatient testing for health care providers. Quest and LabCorp perform 60 percent of all tests for patients not insured by HMOs, and hospital, clinic, and specialty labs perform the balance;¹³⁰

- Most smaller labs, which operate independently, have fewer financial and staff resources than larger competitors to invest in developing and implementing standards;
- Many health care providers are less familiar than labs and other entities with the standards issue. They need more time to cultivate the staff knowledge and organizational capacity necessary to implement new technical specifications;
- Some large commercial labs have determined that the benefits of creating interoperability with small health care providers are not worth the investment in time, capital, and staff; and
- Implementing data standards requires cultural change. Some entities may resist the idea of information exchange with others out of fear that they will lose control of their data, access to the information and internal systems, or competitive advantages.

Federal Requirements

Data exchange occurs in two ways: (1) from labs to the physician who ordered a test, and then from the physician to other clinical care providers, health plans, and/or data clearinghouses; and (2) from labs to RHIOs. In either scenario, state and federal rules, particularly CLIA and the Health Insurance Portability and Accountability Act (HIPAA), may present challenges.

Under CLIA, labs are responsible for the content and format of test results. However, vendors of health information systems tend to change the format in their products so test results will be easier for

providers to read and interpret. Although many of the modifications have been in response to provider requests, labs are nevertheless legally responsible for delivering test results in the CLIA-compliant format.¹³¹ Furthermore, CLIA and some states require that results be sent only to the ordering physician rather than to the physician as well as other designated clinicians, such as nurses and emergency room doctors who are responsible for using the results, and to organizations such as RHIOs.

Under HIPAA, disclosure of information is restricted to “treatment, payment, or operations” activities and labs must have a business associate agreement with RHIOs to exchange data. State and CLIA regulations governing the release of lab information also apply. Some provider groups are addressing the regulatory challenges in innovative ways. In California, for example, sharing of lab results between independent practice associations and other physician groups in a delegated model¹³² and with HMOs or other health plans does not comply with HIPAA’s confidentiality rules.¹³³ In November 2007, the California Association of Physician Groups, which represents 155 such groups, coordinated the signing of a HIPAA-compliant code of conduct and development of a technical toolkit for expanded bidirectional data sharing between medical groups and six major payers in the state: Aetna, Blue Cross, Blue Shield, CIGNA, Health Net, and UnitedHealthcare.¹³⁴ This effort seeks to make data sharing simple, uniform, and as automated as possible, thanks to standards and formats that satisfy multiple reporting specifications. It should lead to lower overhead and more accurate measurement of provider performance and care quality.

Certain CLIA regulations may have to be clarified or revised in order to expand the availability of electronic lab data.

VII. Demonstrating the Value of Laboratory Medicine

The health care industry is increasingly using lab data as an objective, scientific indicator of performance and outcomes.

PERFORMANCE AND OUTCOMES MEASUREMENT USING lab data and other indicators is a way to improve transparency, accountability, and quality. Payers, regulatory agencies, clinicians, and patients are all demanding demonstration of the value of specific aspects of medical care.¹³⁵ Value assessments often address provider performance, patient safety, and intermediate health outcomes. There is growing interest in assessing long-term health and economic outcomes, and provider and consumer satisfaction. The health care industry is increasingly using lab data as an objective, scientific indicator of performance and outcomes.

Performance Measurement

Evaluations of health care performance often are based on compliance with clinical practice guidelines or other established sources of evidence systematically developed by government agencies, medical specialty societies, accreditation organizations, and private insurers. Such guidelines, also known as practice policies, practice parameters, and clinical pathways, help practitioners and patients make decisions in specific clinical and personal circumstances.¹³⁶

There are guidelines for many aspects of health care, including prevention, screening, diagnosis, treatment, rehabilitation, and palliative care.¹³⁷ Among the tools for measuring care quality are treatment recommendations, immunization schedules, practice bulletins, and decision making algorithms.¹³⁸ Comparing patterns of delivered care with these tools or clinical guidelines can reveal information about overuse, underuse, misuse, and appropriate use of health care interventions and resources.¹³⁹

Lab testing has become a key component of public and private performance measurement by entities such as the National Committee for Quality Assurance, the Agency for Healthcare Research and Quality, and RAND (see Appendix C).¹⁴⁰ Their performance assessments look at the appropriate use of lab testing, specified in clinical guidelines, as an indicator of care quality or intermediate health outcomes.¹⁴¹ Quality indicators are the attributes of health care structures, processes, or outcomes that, when measured,

produce accurate estimates of the extent to which providers adhered to standards. Typically, providers are evaluated in terms of whether they appropriately ordered tests for screening, diagnosis, or disease management. There is increasing interest in more extensive outcomes measurement, including studies of variation in practice patterns and utilization, and the effect that greater emphasis on quality, improved care, efficiency, accountability, and patient education has on outcomes.¹⁴²

California illustrates the dynamics of incorporating lab data in performance measurement.¹⁴³ The state has a high degree of integrated health care delivery built mostly on the coordinated care that groups of physicians provide in a very large and diverse market. Historically, pay-for-performance reports based on lab and pharmacy data were distributed about three times a year, but this was too infrequent for point-of-care reminders that help physicians manage patients.¹⁴⁴

To facilitate reporting of lab data for state and national performance measurement, the California HealthCare Foundation developed the California Clinical Data Project (CALINX)—a standard that governs batch reporting of test results to data warehouses and disease registries—through statewide consensus. Quest and LabCorp have adopted CALINX, and several provider groups are successfully using lab data to meet pay-for-performance requirements and performance measures in the Healthcare Effectiveness Data and Information Set (HEDIS).

However, California's unique delegated model of health care—wherein independent practice associations, rather than HMOs, assume financial risk and control a broad range of utilization management decisions—has created several circumstances that affect performance measurement.¹⁴⁵ The associations usually operate

under capitated contracts and other policies that can affect competition for services. If they control costs, they may be rewarded with a larger market share. But this arrangement might not fully reward them for quality and efficiency—if, for example, objective indicators of performance show they properly manage disease.¹⁴⁶ Thus, even though clinical data are increasingly available, purchasers, physicians, and health plans may struggle to appropriately value the data.

Outcomes Measurement

Outcomes indicate changes in patients' health status, their experiences and satisfaction with care, and costs related to care.¹⁴⁷ Outcome measures may include those related to health, such as mortality, morbidity, and adverse events; humanistic issues, such as quality of life and patient and provider satisfaction; and economics, such as cost per test and cost-effectiveness.¹⁴⁸ The most prominent uses of lab test data in outcomes measurement pertain to patient health and the cost of care.

Health Outcomes

The utility of lab test data for measuring health outcomes depends on the association between test results (biomarkers) and patients' long term health. For example, screening for type 2 diabetes with a fasting plasma glucose test and/or oral glucose tolerance test can detect the disease in its preclinical phase. During the 10 to 15 years after clinical diagnosis, tight glycemic control can improve patient outcomes by reducing the risk of blindness and end-stage renal disease.¹⁴⁹ In 2006, failure to regularly test diabetic patients for the amount of glycated hemoglobin in their blood resulted in 7,100 to 15,900 avoidable diabetes-related deaths and \$1.3 billion to \$1.7 billion in avoidable hospital costs.¹⁵⁰

Much research has been devoted to establishing the value of test results, including results from point-of-care testing, as predictors of health outcomes in areas such as thyroid function, neonatal cystic fibrosis, and surgical, pathology-based early diagnosis of breast cancer.¹⁵¹ Lab data are generally underused in outcomes measurement because of the high cost of capturing outcomes data, a lack of standardized data-collection and reporting methods, and a lack of agreement about how to analyze data appropriately—such as whether they should be risk-adjusted. Labs can help reduce the reporting burden on health care providers by creating standardized outcomes databases that integrate administrative and clinical data associated with lab tests.¹⁵² If these databases were to include validated models for predicting the risk of medical complications in high-risk individuals, the effect on health outcomes could be significant.¹⁵³

Economic Outcomes

There is growing interest in the trade-offs between health care benefits and costs, particularly when an intervention exceeds the current standard of care but offers marginal improvements at a significantly higher price.¹⁵⁴ Medicare rarely uses formal cost analyses—such as those related to cost-effectiveness—in establishing coverage policies, although commercial insurers sometimes do. For the most part, public and private payers base coverage decisions primarily on clinical evidence.¹⁵⁵

Cost-Effectiveness Analyses

Cost-effectiveness analyses, which are conducted from the clinician, payer, patient, or society perspective, weigh the health and economic trade-offs of alternative health care interventions. They calculate the incremental cost per incremental unit of effectiveness among the intervention options.

Results are presented as net cost per health outcome, typically the cost per disease case prevented or cost per life saved.¹⁵⁶ Units of effectiveness, or “natural health units,” are the number of disease cases detected or life years saved. A common unit in cost-effectiveness analyses is quality-adjusted life year (QALY), a combination of the quality and length of life.¹⁵⁷ Although payers do not use a standard cost-effectiveness threshold, incremental ratios of between \$50,000 and \$100,000 or less per QALY are generally accepted values.¹⁵⁸

In the laboratory industry, cost-effectiveness analyses have examined screening for HIV and *Chlamydia trachomatis*, genetic testing (including the HER-2/neu gene for breast cancer), immunoassay fecal occult blood testing for colorectal cancer, and nucleic acid testing for the safety of donated blood.¹⁵⁹ For example, in a 2005 study of HIV screening and treatment, researchers used a computer simulation model to compare routine/voluntary HIV counseling, testing, and referral with current practice in terms of the prevalence of undiagnosed infection and the annual incidence of infection. They targeted three groups: high-risk people, those at the threshold of prevalence and incidence (a level set by the Centers for Disease Control and Prevention), and the general population. The researchers found that routine/voluntary screening for HIV once every three to five years is clinically justified and cost-effective in the high-risk and threshold populations, and that one-time screening in the general population may also be cost-effective. In the high-risk group, one-time screening of individuals already infected with HIV was associated with earlier diagnosis of HIV and longer average survival time.¹⁶⁰

Another avenue of research pertains to the cost-effectiveness of different lab testing venues—for example, point-of-care versus central lab facility testing, and home versus clinical site testing.¹⁶¹

These studies assess factors such as the cost of labor and reagents, the potential for shorter turnaround times, and whether point-of-care testing increases or decreases test accuracy. A 2004 study found that, based on data from 445 organizations providing health care, the cost of glucose tests performed at central labs was lower than the cost of glucose tests performed at the point of care. In addition, the latter cost varied and depended on testing volume.¹⁶²

There is little published research on the cost-effectiveness of lab testing.¹⁶³ The health care setting where studies take place, such as hospitals, may limit the applicability of results to other settings, such as ambulatory care. Nevertheless, as payers face increasing scrutiny of their decisions about coverage of new testing technologies, the economic impact of lab testing on the health care system is generating greater interest in cost-effectiveness analysis.¹⁶⁴

Comparative Effectiveness Research

Policymakers, payers, many researchers, and other stakeholders are calling for a national effort to support comparative effectiveness research on the relative risks, benefits, and perhaps costs of alternative interventions, including drugs, devices, and procedures.¹⁶⁵ This type of research emphasizes head-to-head comparisons of health care interventions in real-world settings. Analytic tools include randomized and non-randomized controlled trials in routine health care settings; retrospective analyses of databases, such as claims databases and EHRs; systematic reviews of available evidence; and modeling.¹⁶⁶

Comparative effectiveness research that examines the relative impact of two or more diagnostic tests along the causal pathway between testing and health outcome may show clinicians how a new test improves outcomes relative to a standard test.¹⁶⁷

Analyses indicating that lab tests are more clinically

effective or cost-effective than other diagnostic procedures, such as imaging, could prompt greater use of lab tests among physicians. In addition, such research may prompt manufacturers to focus on studying, developing, and validating tests in real-world settings.¹⁶⁸

Policymakers' interest in comparative effectiveness research as a way to understand and control health care spending has grown in the past several years. The Enhanced Health Care Value for All Act of 2007, introduced in the House of Representatives, would amend the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to expand the scope of research related to the comparative effectiveness of health care items and services.¹⁶⁹ The legislation calls for appropriating \$3 billion to the Agency for Healthcare Research Quality over the next five years for this purpose. The Comparative Effectiveness Research Act of 2008, introduced in the Senate, would create a private, nonprofit entity to fund and coordinate federal comparative effectiveness research activities, and appropriate \$400 million for research.¹⁷⁰ Despite congressional interest in this type of research, resulting changes may not have a significant effect on health care spending for up to 10 years.¹⁷¹

VIII. Conclusion

Laboratory medicine will play a more prominent role in repairing the system as stakeholders increasingly demand scientific evidence for clinical decision making and strategies to address the significant shortfalls in quality, outcomes, and cost.

THE CONVERGENCE OF MULTIPLE FACTORS, INCLUDING the rising cost of health care, the growing number of uninsured and underinsured people, the aging population, and the greater prevalence of chronic diseases, is severely challenging the health care system. Laboratory medicine will play a more prominent role in repairing the system as stakeholders increasingly demand scientific evidence for clinical decision making and strategies to address the significant shortfalls in quality, outcomes, and cost.

Current trends related to lab testing include:

- The testing market has grown steadily during the past decade in terms of spending, revenue, and test volume. It will continue to expand in the years ahead, especially as new genetic tests and molecular diagnostics become available;
- Although testing takes place in a variety of settings, the main competitors for moderately and highly complex tests are hospitals and independent labs. Two companies—Quest and LabCorp—now dominate the national independent lab market as a result of consolidation in recent years. Large and small labs each have distinct competitive advantages they may leverage to maintain or increase market share;
- For labs, payers' reimbursement policies present the biggest challenge to market growth. Policies regarding certain tests, especially genetic tests and molecular diagnostics, are inconsistent or vary. Another hurdle is administrative and financial burdens related to billing for bundled outpatient hospital services. If Medicare ultimately imposes competitive bidding for lab services, it would reduce the amount that labs can bill for tests;
- Technological advances have spawned new kinds of tests and procedures that raise important federal and state regulatory oversight issues. Among these issues are testing standards, the qualifications of lab personnel, and the regulation of tests that labs

develop in-house. Serious gaps in regulations regarding genetic tests could compromise patient and public health;

- Greater reliance on consultations between clinicians and labs is one of the most promising ways to prevent inappropriate use of tests and misinterpretation of test results;
- A major concern throughout the lab sector is the growing shortage of workers, particularly at the technologist/scientist and technician levels;
- Health information systems can deliver critical lab data to clinicians at the point of care and help improve quality. Technological advances, including EHRs, Web-based applications, computerized physician order entry, clinical decision support systems, and laboratory information systems, along with greater use of data standards, are changing the way labs communicate with health care providers and patients, and how they deliver services, educate their workforce, market themselves, and track clinical information. However, unresolved technical, business, and regulatory challenges are stifling ubiquitous data sharing; and
- Although lab data play a key role in performance measurement, including assessment of health outcomes, the high cost of data capture and the lack of standards for data collection and reporting are among factors that have hindered analysis. Two performance measurement tools are cost-effectiveness analyses and comparative effectiveness research. Widespread interest in the latter as a way to contain costs and improve health care quality has recently prompted federal legislation that seeks to promote such research.

Appendix A: Waived and Non-Waived Tests

All labs must register with the Centers for Medicare & Medicaid Services, obtain certification for a certain level of testing complexity, and comply with the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The FDA is responsible for lab test categorization, including test complexity and waiver determinations.

Waived tests are relatively simple and accurate; erroneous results, the likelihood of which is negligible, pose no reasonable risk of harm to patients. They include tests the FDA has approved for home use. Facilities that perform them are not subject to many of the CLIA recommendations.

Non-waived tests are moderately or highly complex, could pose a risk to patients if results are incorrect, and are subject to all CLIA requirements.

Provider-performed microscopy, a subset of non-waived tests, encompasses a few procedures that are typically done in doctor offices, such as wet and potassium hydroxide (KOH) preps. While exempt from routine inspections, facilities that perform these particular types of tests must comply with other CLIA requirements.

The number of waived tests has increased dramatically in recent years, due in part to simplification of testing procedures and advances in instrumentation. Tests that once were considered moderately complex have been redesigned, and if they meet FDA criteria for simplicity and accuracy, the agency may grant them waived status. In 1993, the FDA waived about 200 tests associated with nine analytes; in 2004, it granted such status to more than 1,600 test kits associated with 76 analytes.¹⁷² Many of these are simplified, miniaturized, point-of-care versions of more complex tests. Consequently, use of waived tests during patient visits is increasingly attractive to ambulatory care physicians who seek to

improve convenience for patients and lower practice overhead.

Appendix B: Lab Data Standards Initiatives

Efforts to standardize lab data include:

- The American Health Information Community (AHIC), a federal body that advises the secretary of the Department of Health & Human Services, seeks to accelerate the development and adoption of health information technology, including lab data integration with EHRs;¹⁷³
- The Healthcare Information Technology Standards Panel, established by the American National Standards Institute, provides input to AHIC. The panel develops national interoperability specifications, implementation guides, code sets, terminologies, integration profiles, and information policies. It has recommended interoperability standards, including some for lab results reporting in EHRs;¹⁷⁴
- In 2006, the Office of the National Coordinator for Health Information Technology at the Department of Health & Human Services hosted a meeting to evaluate data exchange for lab test orders and results reporting.¹⁷⁵ Participants included national labs, health care providers, professional groups, technology vendors, and other leaders. The meeting identified business, financial, regulatory, data security, privacy and confidentiality, technical, and patient identification issues that must be addressed to more fully integrate lab data with EHRs and other applications;
- Two initiatives at the California HealthCare Foundation are the EHR-Lab Interoperability and Connectivity Standards project (ELINCS) and the California Clinical Data Project (CALINX). ELINCS developed standard and detailed specifications for coding and formatting lab results messages delivered in real time from laboratory information systems to EHRs.¹⁷⁶ Independent commercial labs and hospital labs can use the standard to send test results electronically, and technology developers and vendors can use it in designing EHR systems.¹⁷⁷ CALINX is a standard to retrospectively communicate batch reporting of lab test results to data warehouses and disease registries for population-level quality improvement;¹⁷⁸
- In 2003, the Healthcare Information and Management Systems Society extended its Integrating the Healthcare Enterprise initiative to include labs.¹⁷⁹ The international, private-sector initiative developed a technical framework that defines exchange partners, data exchange standards, and guidelines for integrating lab information and automation systems with larger health care enterprises, such as hospitals and integrated delivery systems.¹⁸⁰

Appendix C: Performance Measurement Initiatives

Efforts to standardize quality measurement and reporting in health care have been under way for more than 15 years.¹⁸¹ Largely driven by federal and private payers and accrediting organizations, early leaders in performance measurement include the Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, the Joint Commission, and the National Committee for Quality Assurance (NCQA), a coalition of private health plans.

NCQA's Health Plan Employer Data and Information Set (HEDIS) is one of the most successful quality measurement initiatives to date, enabling employers and consumers to reliably compare health plans. HEDIS consists of 71 quality measures—such as whether a patient received beta blocker treatment after a heart attack—covering eight domains: effectiveness, access/availability, satisfaction, health plan stability, use of service, cost of care, informed health care choice, and health plan descriptive information. Private health plans seeking accreditation by NCQA and public payers that participate in Medicare must report on the HEDIS measures.¹⁸² Among employers, nearly 90 pay-for-performance programs also use them.¹⁸³

Other organizations that have joined efforts to develop, coordinate, and harmonize performance measurement and reporting include the Pacific Business Group on Health, the Leapfrog Group, the American Medical Association, the Hospital Quality Alliance, the AQA, the Foundation for Accountability, and the National Quality Forum. Standards and requirements for quality assessment, performance measurement, and public reporting have extended to long term and ambulatory care settings.

In addition, the National Quality Forum is developing performance measures for more specific

patient populations, such as children and the elderly; health conditions, such as substance abuse disorders and venous thromboembolism; and infrastructure, such as health information technology.

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