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Check out our new look & improvements!

From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

A New Look and New Services for THE DARK REPORT

YOU'VE PROBABLY ALREADY NOTICED that this issue of THE DARK REPORT sports a new look! We took advantage of the New Year to deliver a fresh, new appearance to THE DARK REPORT while preserving all that's unique and most valued by our long-time clients and regular readers.

Refinements to our established format are designed to make it easier and faster for you to see the information you want. Just as our editorial style has achieved a recognition for clarity and ease of reading, so also do we want the overall appearance of this publication to improve the value you gain from each issue.

This is another step in our ongoing effort to bring you the most relevant and most useful business intelligence and analysis in the laboratory industry. That was the motivation behind the launch of *www.darkdaily.com* in September. Our daily e-briefings have not only proved to be a big hit, but the ability of DARK Daily readers to immediately e-mail comments back to us has opened a new opportunity to report news and breaking events almost as fast as they occur.

For those of you who haven't looked at *www.darkdaily.com* yet, it's time that you did. Each DARK Daily e-briefing is a short, quick-to-read analysis about important developments in the laboratory industry. It's already caused a stir and raised the competitive bar within the lab industry. Take a moment and sign up today. When you do, you'll be pleasantly surprised to learn that DARK Daily comes directly to your desktop at no charge! It's free!

What other improvements are ahead for THE DARK REPORT this year? I can't let all our cats out of the bag, but I can reveal that the *12th Annual Executive War College on Lab and Pathology Management*, scheduled for May 10-11, 2007 in Miami, Florida, will have some notable additions. Both first-timers and regular attendees will get extra value from the new features at this year's program.

Also, stay tuned for an announcement in a month or so about another new service from THE DARK REPORT. It will be launched in the fall and is designed to support one of the most important management strategies to hit the laboratory industry in the past four decades. Finally, thank you for all your support during the years. Be assured that we are working hard to help you keep your laboratory at the peak of success! TDR

Key Trends Drive Change For Clinical Laboratories

Healthcare trends and industry trends are putting pressure on laboratories to change

CEO SUMMARY: Technology plays an ever-growing role in reshaping the organization and operation of clinical laboratories. New technologies figure prominently in THE DARK REPORT's 2007 list of key trends in the clinical laboratory industry. Technological advances in instrument systems, informatics, and molecular diagnostics are giving laboratories new tools to improve clinical services and streamline lab operations.

By Robert L. Michel

EVERY SECOND YEAR, we present our list of current trends influencing clinical laboratories. The goal is to identify the forces acting upon clinical laboratories and pressuring them to change and respond in appropriate ways.

Armed with knowledge and understanding about these trends, pathologists and laboratory administrators can act in a timely fashion to develop strategies to keep their laboratory organizations competitive and profitable. Also, *in vitro* diagnostic (IVD) manufacturers and laboratory informatics vendors can use these trends to better position their products and services to meet the needs of their customers.

The 2007 macro trends for clinical laboratories can be divided into two primary groups. One group of trends describes major changes in the American healthcare system that directly influence or require laboratories to respond and change the way they serve clinicians and the healthcare establishment.

Included in this group of trends are such factors as how Lean and Six Sigma methods are becoming more widespread in both the hospital and the laboratory industry, how enrollment in high-deductible health plans (HDHPs) continues to grow, and how provider pay-for-performance (P4P) is becoming a given in the U.S. healthcare system.

The second group of trends describes specific developments within laboratory medicine that alter the status quo. These trends are uniquely directed to the organization and operation of clinical laboratories.

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $13.10 per week in the US, $13.70 per week in Canada, $14.85 per week elsewhere (billed semi-annually).

Reviewing 2001 Trends For Clinical Laboratories

IT WAS 2001 WHEN WE PRESENTED our first list of clinical laboratory trends, and here's a review:

1. **CONSUMERS ARE HERE!** Remember all the hoopla about direct access testing (DAT) and consumer activisim in healthcare? It's there, but at such a small level as to hardly register on the scale.
2. **CLINICAL DATA REPOSITORIES.** THE DARK REPORT recognized the threat and the opportunity for clinical labs as clinical data repositories (CDRs) were established in communities across the country. Today, the hot term is Regional Health Information Organization (RHIO) and regional CDRs are more concept than reality.
3. **WEB-BASED LAB TEST REPORTING.** In 2007, this is a common feature. Back in 2001, it was a concept just gaining traction in the marketplace.
4. **LAB REGIONALIZATION.** This trend has not played out during the past six years. Across the United States, there's been little increase in the number of regional lab organizations. Instead of an external strategy (regionalization), labs concentrated on internal strategies.
5. **E-HEALTH SERVICES.** THE DARK REPORT pointed out that the first generation of e-health companies was failing (**MedUnite**, **DrKoop.com**, and others), but a number of healthcare services were steadily evolving onto Internet platforms.
6. **INCREMENTAL AUTOMATION.** THE DARK REPORT is first to pick up the increase in lab interest for specific automation solutions, such as pre-analytical, workstation consolidation, and task-targeted automation.
7. **MED TECH AVAILABILITY.** THE DARK REPORT connects recognition of the MT shortage as a major reason why lab directors were implementing labor substitution projects. Automation is a popular strategy and interest in quality management methods ticks up.
8. **MANAGEMENT PHILOSOPHY.** THE DARK REPORT notes the ISO:9000 certification by **Quest Nichols Institute** and **Kaiser Northwest Laboratory**, as well as the launch of J&J's **Ortho-Clinical Diagnostics'** Lean/Six Sigma consulting service.

In this second group of trends are the resurgence of local laboratories—but as hospital laboratory outreach programs, the growing use of EMRs by referring physicians, the emphasis on outcomes in lab accreditation programs, the ever-growing skilled labor crisis, more automation in labs, the move to middleware, a steady increase in the number of specialized testing laboratory companies, the erosion of the "wall" between clinical laboratory and anatomic pathology, Medicare's pending laboratory competitive bidding demonstration project, real-time QA/QC, and the impending evolution in lab instruments.

There is also a unifying theme to many of the 14 macro trends facing clinical laboratories. It is the drive to improve the quality of healthcare. Across the American healthcare system, all sorts of stakeholders are developing programs that have the ultimate goal of improving health outcomes.

This emphasis on quality was not present in our 2001 list of clinical laboratory macro trends. In fact, in 2001, THE DARK REPORT knew of no example of a clinical laboratory that had used Lean and Six Sigma quality management methods to effect a major re-engineering of core laboratory work processes. That is certainly not the case in 2007. Use of Lean and Six Sigma methods is about to go mainstream in the American laboratory industry.

At the start of this New Year, all of us at THE DARK REPORT hope that you find these 14 clinical laboratory macro trends helpful. We also encourage you to e-mail us with your comments and contributions to this evolving list of clinical laboratory macro trends.

Contact Robert Michel at labletter@aol.com.

Lab Industry Macro Trend #1

Lean and Six Sigma Methods Set Deepening Roots in Labs

USE OF QUALITY MANAGEMENT METHODS in laboratories and hospitals is spreading, not just in the United States, but throughout the world. In particular, Lean techniques seem to be emerging as the most preferred approach.

Prior to 2006, it was "first mover" laboratories and hospitals which experimented with Lean, Six Sigma, and other management systems. Now quality management programs are being launched by "early adopter" laboratories and hospitals.

This will further broaden the base of support for quality management methods in the laboratory profession and the hospital industry. Expect to see ever-increasing numbers of these quality practitioners publishing papers and writing stories about the outcomes of their Lean and Six Sigma projects. As this body of evidence increases, it will encourage further increases in the numbers of laboratories and hospitals which adopt and utilize Lean, Six Sigma, and other quality management systems.

THE DARK REPORT predicts that it won't take more than another 36 months for Lean and Six Sigma programs to move from early adopter laboratories and hospitals to the mainstream of both industries. That's because effective use of quality management methods in laboratories has consistently unlocked remarkable improvements in average test turnaround time, labor productivity, and reduction of errors and waste. That was certainly the case at **Sonora Quest Laboratories** in Phoenix, Arizona. In recent years, its deep embrace of quality management has transformed the organization into one of the region's most respected laboratory providers. At the beginning of 2006, Sonora Quest announced that it had won the Arizona Quality Program's highest honor—the Governor's Award for Quality. *(See TDR, February 6, 2006.)*

Sonora Quest is an example of a "first mover" laboratory. An "early adopter" example is **Christian Hospital**, part of **BJC HealthCare** in St. Louis, Missouri. It has successfully applied Lean methods in a major redesign of workflow in its core laboratory. *(See TDR, March 20, 2006.)*

Laboratory directors and pathologists should not overlook another consequence of greater use of Lean and Six Sigma within the laboratory industry. A laboratory that effectively utilizes quality management methods gains a competitive advantage over those laboratories which do not. This raises the performance bar for all laboratories in a region.

Now that the lab industry's first movers and early adopters have repeatedly demonstrated how Lean, Six Sigma, and other quality management systems can improve service, boost labor productivity, and raise quality, it won't be long before the lab industry mainstream adopts Lean, Six Sigma, and other quality methods.

Lab Industry Macro Trend #2

Resurgence of Local Labs— But Most Are Owned by Hospitals

OVER THE PAST FIVE YEARS, hospital laboratory outreach programs have filled the local laboratory vacuum left after independent laboratory companies were sold by their owners to public laboratory companies during the 1990s.

This development has gone unheralded. In community after community since 2001, hospitals and health systems have launched laboratory outreach programs. Many times the initial lab outreach effort was organized only to serve office-based physicians owned by the parent hospital or health system. As the outreach program gained experience and resources, sales and marketing commenced to other office-based physicians in the community.

There is another interesting aspect to this growth in hospital laboratory outreach programs. In many communities, after the independent laboratory was acquired by a national lab company, the national lab would close down the acquired laboratory facility and consolidate the testing into one of its existing regional laboratory facilities.

This had two consequences. It left many medical technologists and other trained lab staff unemployed in smaller communities. It often also caused a decline in service, since physicians were now served from a laboratory facility that was located hundreds, even thousands, of miles away.

The resulting situation was recognized as a business opportunity by the local hospital. It had a ready pool of med techs available to hire, along with local service reps and sales people eager to leave the national lab company and bring their client relationships to the hospital's outreach program.

Further, THE DARK REPORT has written about the economic pressures on hospital administrators and laboratory directors which have encouraged them to develop outreach programs as a way to increase the volume of specimens tested in the laboratory, thus lowering the overall average cost per test for inpatient testing. *(See TDR, June 12, 2006.)*

Together, the economic pressure and the obvious opportunity to provide a local lab testing service have encouraged the creation of a substantial number of hospital laboratory outreach programs across the United States. Collectively, these lab outreach programs are nibbling at the market share held by the two blood brothers.

In fact, the best of these outreach programs are tough competitors. Examples are **NorDx Laboratories** in Scarborough, Maine, and **DSI Laboratories** in Fort Meyers, Florida, in the East, **Central DuPage Hospital** in Winfield, Illinois, in the Midwest, and **PAML/PACLAB** in Washington State and **John Muir Medical Center** in Walnut Creek, California, in the Far West. The success of these hospital outreach programs against the national laboratories shows that it is possible to compete and grow.

Lab Industry Macro Trend #3

Growing Use of EMRs by Docs Requires Response by Labs

IF IT'S NOT ON YOUR LAB'S RADAR SCREEN TODAY, IT SOON WILL BE. The need for laboratories to link into the physician's EMR (electronic medical record) system is fast becoming a competitive requirement to win and retain big clients.

Across the United States, the nation's largest medical clinics and physician group practices are implementing EMR systems. These clinics and groups typically refer the greatest number of specimens to their laboratory providers. As physicians in these clinics and groups begin using EMRs in their daily practice, they want to electronically connect to their laboratory provider for lab test ordering and results reporting.

In order not to lose these important client accounts, laboratories are taking active steps to create electronic "gateways" between their laboratory information system (LIS) and the physicians' EMRs. Because speed in execution is often an important consideration, many labs are opting to have a third-party software vendor create the programming necessary to meet the physicians' request.

Lab-to-physician-EMR gateways differ from the current generation of Web browser-based lab test ordering and results reporting systems. Today's Web browser-based systems are created by the laboratory and are designed to interact with the existing LIS and the lab's various rules engines. Ordering physicians access them through their Web browsers.

It is not so simple when the laboratory wants to electronically connect to the physician's EMR. Many EMR systems are designed to support direct computerized physician order entry (CPOE), along with a clinical decision support system, and a clinical knowledge data base.

Because physicians are working within their EMR system as they see a patient, they want the ability to order tests directly from the screen of their EMR. Similarly, they want laboratory test results to be automatically downloaded into the EMR and to populate the individual medical records in the format required by that EMR system.

Both of these requirements complicate the task of the laboratory when it wants to electronically enable lab test ordering and results reporting between its LIS and the client doctor's EMR. The lab's software vendor needs to write an interface that allows the EMR to build lab test orders consistent with the laboratory's test catalog and ordering rules. Another complicating factor is that each different EMR system requires the laboratory to create a customized gateway between its LIS and the physician's EMR system.

Combined, these factors explain why many independent labs and hospital laboratory outreach programs are actively developing interface gateways. To compete successfully for office-based physician clients, it is fast becoming a competitive requirement to provide clients with an LIS-to-EMR gateway interface.

Lab Industry Macro Trend #4

High-Deductible Health Plans Continue to Gain Enrollment

ENROLLMENT IN CONSUMER-DIRECTED HEALTH PLANS (CDHPs) and health savings accounts (HSAs) grew steadily, if not spectacularly, over the past 12 months.

This is a direct consequence of the recent policy change by employers and government health officials. The goal is to use consumer-directed health plans (CDHPs) to motivate consumers to become savvy purchasers of their health care. As this occurs, it is believed that the quality of health care will improve even as the year-to-year increases in health costs moderate.

Typically, a CDHP is a high-deductible health plan. Some CDHPs are combined with a tax-advantaged savings account, like an HSA or HRA (health reimbursement account). HSAs are employee-owned and fully portable, meaning workers can retain account balances if they leave their job. Both employees and employers can contribute to HSAs, but employer contributions are optional. *(See TDR, December 26, 2005.)*

The idea is that CDHPs will motivate employees and their family members to take more responsibility for their health care decisions. At the same time, employers and health plans would help make patients better consumers by giving them information about providers and treatment options.

Forrester Research projects that CDHP enrollment levels, already at 2% of the insured population, will be 24% of insured beneficiaries by 2010. In a report issued by **Celent Communications**, HSA enrollment is expected to increase from about six million currently to 15 million by 2010 and 30 million in 2015, which would represent about 17% of the enrolled population.

What lab directors and pathologists should recognize is that the shift to CDHPs is the consumer movement growing from a different direction. During the second half of the 1990s, health policy makers believed that a steadily increasing number of activist consumers were going to "take charge" of their healthcare. That didn't happen, and was one trend that THE DARK REPORT predicted which didn't unfold as expected.

But now, seven years later, the role of the consumer in choosing his or her provider—and being responsible for direct payment of up to several thousand dollars to that provider—is growing. The driver behind this dramatic shift is the coordinated effort by employers and the federal government to make consumers the primary buyers of healthcare.

This is a trend which will not be derailed, for a simple reason: money. Neither employers nor the federal government can afford the year-to-year increases in the cost of health benefits. High-deductible health plans (HDHPs) and HSAs underpin a major healthcare cost containment effort. For that reason, it is likely efforts to expand CDHP enrollment will continue.

Lab Industry Macro Trend #5

Emphasis on Outcomes Seen In Lab Accreditation Programs

LAST FALL, TWO SIGNIFICANT DEVELOPMENTS gained little attention from the national media or the healthcare industry.

First, the **National Committee for Quality Assurance** (NCQA), in Washington, D.C., released its *2006 State of Health Care Quality* report. This report documented continued improvement in the quality of health care on a large scale. It also demonstrated the need to apply its measurement systems to the entire American health system. NCQA noted that, for health plans providing HEDIS (Health Plan Employer Data and Information Set) data to NCQA, there was improvement in 35 out of 42 HEDIS measures of clinical care.

NCQA's report is significant because it helps to establish a clear link between public reporting and quality improvement. NCQA notes that even a 2% increase in hypertension control rates means 82,000 more Americans have their blood pressure at acceptable levels, causing heart disease and stroke rates to drop.

HEDIS data comes with a catch. Only 76 million of 176 million Americans in health plans are represented by the NCQA's data. However, for the first time, PPOs (preferred provider organizations) now provide HEDIS data. During 2006, more than 80 PPOs, representing 14 million Americans, supplied HEDIS data to NCQA.

NCQA is not shy about extrapolating the benefits of improved healthcare. It says that as many as 150,000 deaths could be averted and as much as $100 billion could be saved each year if the entire U.S. health system raised its performance to the benchmark levels NCQA seeks for all health plans.

The second significant development involves accreditation inspections. Last year, the **College of American Pathologists** (CAP) began unannounced routine inspections for laboratories. *(See TDR, February 27, 2006.)* The next logical step will be accreditation based on clinical outcomes. **The Joint Commission on the Accreditation of Healthcare Organizations** (JCAHO) is already integrating outcomes and other performance measurement data into its accreditation process.

In addition, laboratories worldwide are seeking accreditation that helps them relate their regional performance to that of laboratories in other countries. One effective way to do so is to measure results based on clinical outcomes. Another source of change may be the growing use of international standards such as ISO 15189–Medical Laboratories.

For labs, hospitals, and other providers these trends foreshadow tightening accreditation standards. It is likely that accreditation bodies will seek outcomes data and ask that labs demonstrate improvement in specified outcomes from one inspection period to the next.

Lab Industry Macro Trend #6

Provider "Pay for Performance" Is Now A Given in the U.S.

IT WAS A FUNNY THING that happened to physician pay-for-performance (P4P) programs in the past year. P4P went from being a subject that some physician associations criticized regularly to becoming an opportunity that could lift the professional and financial fortunes of physicians nationwide.

Although the **American Medical Association** (AMA) and other physician associations continue to critique the concept of physician pay-for-performance, they now acknowledge that P4P is inevitable.

In June, AMA Secretary John H. Armstrong, M.D., said P4P could serve as a positive force in health care if designed to improve the effectiveness and safety of patient care. "Fair and ethical pay-for-performance programs are patient-centered and assess physician performance with evidence-based measures," he said.

In November, researchers from the **Harvard School of Public Health** published a study of 242 health plans offering commercial HMO products. Researchers determined that 52.1% of health plans—representing 81.3% of people enrolled in HMOs—already used physician pay-for-performance programs. More than half of the HMOs surveyed included P4P in their provider contracts.

These researchers reported that almost all physician P4P programs included measures of clinical quality. The most common clinical care indicators measure the use of asthma medication, diabetes care, and mammography. These specific indicators incorporate the appropriate use of evidence-based care. One interesting note was the discovery that about one third of physician-oriented incentive programs rewarded only the top-rated physicians or groups and not those who improved the most.

The important point here is that the debate is over about whether or not physician pay-for-performance programs should be implemented. P4P now has an accepted role in the American healthcare system.

Going forward, laboratories and pathology group practices can expect to see two developments. First, as more physicians find a larger portion of their clinical services are covered by a P4P program, they will have a financial motivation to improve outcomes. That is likely to encourage them to seek out laboratories and pathology groups that can provide the type of clinical support that can help them raise their outcomes and practice a more effective brand of medicine. Labs providing that higher level of support should enjoy a competitive advantage.

Second, the day is approaching when pathologists and clinical laboratories will begin to see P4P clauses in their contracts with health insurers. That will position laboratory providers to benefit whenever they deliver improved outcomes to their clinicians and patients.

Lab Industry Macro Trend #7

Skilled Labor Crises Looms For Clinical Laboratory Industry

IF ONE TREND IS FOREMOST on the minds of laboratory directors and pathologists, it's the shortage of medical technologists, cytotechnologists, histologists, and other professionals with the technical skills needed by clinical labs.

This trend has two primary consequences. First, in today's tight labor market, many laboratories face a chronic shortage. They find it difficult—and sometimes impossible—to recruit and retain the FTEs authorized for their laboratories.

Last year, the **American Society for Clinical Pathology** (ASCP) said almost half (44%) of all laboratories in a survey reported trouble finding medical laboratory personnel. Staff vacancies for certified medical technologists were highest in the West and Northeast.

Second, in the near future, the impending retirement of a large proportion of the laboratory workforce will exacerbate the shortage of technically trained labor. Anthony Williams, founder and CEO of the **Histotech Exchange, LLC**, a recruiting firm in Lexington, Virginia, told THE DARK REPORT last year that 50% to 70% of histotechs were planning to retire within 10 years.

In 2000, 13% of the U.S. workforce was 55 and older. By 2010, 17% of the workforce will be 55 and older. The youngest baby boomers were born in 1964, meaning critical shortages of qualified workers will soon occur. These are likely to affect service companies most severely, according to the **AARP**.

One major effect of the growing shortage of professionals for technical positions is increased labor costs. The ASCP survey reported that the median average hourly wage increased about 3.5% per year, while salaries rose about 7% between 2003 and 2005. Salaries tend to be higher in hospital and reference laboratories and lower in physicians' office labs.

Another consequence of the labor shortage is that laboratories ask staff to work more hours. While most laboratories reported their staff worked 8-hour shifts last year, 30.5% of labs in the ASCP survey said work shifts could vary by four hours, adding to labor costs.

There is no overnight solution to the shortage of skilled laboratory professionals. For one thing, existing training programs do not have the capacity to handle enough students to close the gap between demand for technologists and the supply.

The shortage of skilled laboratory professionals is one of the primary reasons why the use of automation and middleware in hospital laboratories has increased steadily over the past six years. *See Trends #8 and 9, pages 12 and 13.)* Lab managers are taking steps to boost productivity as one way to cope with FTE vacancies that they cannot fill.

Another consequence of short-staffed laboratories is that existing staff are asked to work longer hours per week. This raises the stress level and can contribute to an erosion in quality and performance.

Lab Industry Macro Trend #8

More Automation In Labs, Including Histology Solutions

AUTOMATION IS STEADILY ADVANCING in sophistication and usefulness. Automation is also moving into new areas of the laboratory. For example, histology is the latest section of laboratory operations to see multiple automated solutions hit the marketplace.

There are now multiple solutions for automation in the core laboratory, where high volumes of routine chemistry and hematology tests are performed. The same is becoming true for other areas of the laboratory, as *in vitro* diagnostic (IVD) manufacturers engineer automation features into instrument systems used from immunology to microbiology and histology.

THE DARK REPORT was first to call attention to the impending introduction of automated systems for histology by several companies. During the past two years, these vendors began shipping their automated systems to laboratories. *(See TDR, January 24, 2005.)*

At the *Executive War College for Laboratory and Pathology Management* in Miami, Florida, last May, a special one-day program was organized around automation in the histology laboratory. Some of the earliest laboratory users of the next-generation products from **Dako**, **Sakura Finetek**, and **Ventana Medical Systems** reported on their experiences.

What motivated these first-mover laboratories to acquire and use automated histology systems was a combination of two factors. One, use of automation was a labor substitution strategy. Recognizing the acute shortage to skilled histotechnologists in their communities, these laboratories were willing to invest in automation as a way to improve productivity of the existing staff.

Two, these first-mover laboratories recognized that quality standards in laboratory operations are tightening. Their use of automation in the histology laboratory was expected to reduce variability in work processes, cut the rate of errors, and improve the overall quality of the finished slides.

It is equally true that increasing labor productivity and improving the quality of work processes have motivated clinical laboratories to acquire and deploy various automation solutions throughout the lab facility. In recent years, the clear preference has been to use targeted automation solutions over TLA (total laboratory automation). For these reasons, sales of pre-analytical automation, task-targeted automation, and consolidated workstation arrangements have been strong.

THE DARK REPORT predicts two things on the lab automation front. First, IVD manufacturers will continue to bring smaller and more productive automation products to market, increasing choices for lab directors. Second, the chronic shortage of medical technologists in most communities will continue to motivate laboratories to continue pursuing automation in their facilities.

Lab Industry Macro Trend #9

Fewer LIS Upgrades Because Labs Opt for "Middleware"

THIS MIGHT BE CHARACTERIZED as the "middleware era." In recent years, many laboratories have become heavy users of middleware solutions.

Moreover, the source of the middleware solutions is often one of a handful of companies that specialize in middleware. There are several reasons why laboratories no longer rely exclusively on their LIS (laboratory information system) and LIS vendor as the source for software solutions to operational needs.

First, hospitals and health systems are devoting ever-greater amounts of money to integration of their clinical data repositories and supporting an electronic medical record (EMR). The nation's largest health informatics companies have responded to this spending priority by shifting resources away from upgrades and updates to their menu of software systems for laboratory, pharmacy, radiology, and other clinical services.

Thus, when many laboratories contact their LIS vendor about programming new functions, they learn it will take considerable money and many months to get that function programmed. That is why many laboratories turn to third-party software companies and ask them to write the software applications needed to accomplish the lab's goals. *(See TDR, June 12, 2006.)*

This aptly describes that class of companies which sprang up to provide software and assistance to allow laboratories to enable Web browser-based lab test ordering and results reporting between physicians' offices and labs over the past decade. Some examples of companies that provide this type of middleware are **4Medica**, **Atlas Medical Software**, **CareEvolve**, **Halfpenny Technologies**, and **Labtest.com**.

Middleware vendors offering solutions to help laboratories in their daily operations and management have also emerged in recent years. Included in this category are companies such as **Data Innovations**, **Inc.**, **Dawning Technologies**, **Inc.**, **Management Decision Systems**, **Inc.**, and **Technidata America Medical Software.**

Middleware is a growing segment of the lab marketplace because lab directors and pathologists are seeking software solutions that will improve work flow through the laboratory and generate detailed data in real time. The goal is to give laboratory managers the information they need to quickly spot problems and more closely manage work processes.

These are reasons why middleware is increasingly used to supplement and add functions to the existing LIS. Further, shortages of skilled laboratory labor, more sophisticated use of laboratory automation, and the need to more closely manage work processes are all additional reasons why the use of middleware is likely to increase steadily in future years.

Lab Industry Macro Trend #10

Steady Increase in Number Of Specialized Testing Labs

When it comes to independent laboratory companies, the business model on the upswing is that of the specialty lab test company. The number of lab firms offering specialized testing services, particularly those based on either patent-protected or proprietary technology, is growing steadily.

This form of independent laboratory company has several important differences that distinguish it from the long-standing business model of the independent commercial lab company that provides routine testing services to office-based physicians.

As noted in Trend #2 *(on page 6)*, local independent lab companies providing routine testing services to office-based physicians have almost disappeared in most cities around the United States. In large measure, hospital laboratory outreach programs have stepped into this vacuum to become the local laboratory resource to the community.

But when it comes to specialized laboratory tests, the marketplace is filling with new companies ready to offer reference and esoteric tests based on the patent-protected or proprietary technology they hold. In fact, this is one of the hottest growth areas for clinical diagnostics.

It must be noted that many of these specialized laboratory companies are not clinical laboratories in the traditional sense. That is because the test menu they offer often involves both clinical pathology and anatomic pathology procedures. New genetic knowledge and rapid advances in technology are allowing biotech companies to identify disease markers, then develop useful clinical assays that they can bring to market.

One of the earliest of these companies was **Myriad Genetics, Inc.**, of Salt Lake City, Utah, which began offering its BRACAnalysis genetic test for hereditary breast and ovarian cancer in the late 1990s.

During the past 24 months, **Genomic Health, Inc.,** of Redwood City, California, and **RedPath Integrated Pathology, Inc.,** of Pittsburgh, Pennsylvania, both entered the market with patent-protected molecular pathology assays.

Genomic Health's Oncotype DX test is used to predict the likelihood of breast cancer recurrence and the likelihood of chemotherapy benefit in early-stage breast cancer patients. RedPath Integrated Pathology offers assays which aid in definitive diagnosis of pre-cancerous conditions, as well as guiding treatment decisions.

Since their launch, both companies have seen a steady growth in specimen volume and revenue. Each company's success demonstrates that the clinical market is ready to accept new diagnostic assays that are supported by clinical studies that provide evidence of their clinical usefulness.

Specialized lab test companies are likely to expand their share of the market. Over time, that will introduce new competitive dynamics into the lab testing marketplace.

Lab Industry Macro Trend #11

Genetic and Molecular Tests To Further Integrate Lab & Path

REMEMBER THE PREDICTIONS OF THE EARLY 1990S? It was widely suggested that genetic knowledge and new technology would combine to make it possible to diagnose all sorts of diseases from a blood specimen.

In such a world, clinical laboratories would be preeminent and anatomic pathology would see its role shrink. This would occur because of the ease of collecting blood versus tissue.

Fast forward to 2007. Genetic knowledge and new technologies are combining to make it possible to use tissue to produce more specific diagnoses for clinicians.

As a result, certain clinical areas of anatomic pathology are booming. This is particularly true in oncology, where molecular technologies now make it possible for a pathologist to take a tissue specimen collected and used in the primary diagnosis of cancer and perform molecular assays on that same specimen that help identify cancer subtypes, guide therapeutic choices, and predict the likelihood of cancer recurrence in the patient.

Within the clinical laboratory, use of molecular technologies has also made significant progress. This is particularly true in infectious disease testing. The number of molecular assays which utilize a blood specimen continue to increase.

The examples of oncology and infectious disease testing show how genetic knowledge and molecular technologies are creating new tools for both the clinical laboratory and the pathology laboratory. One consequence of this development is that the traditional—and clearly recognized—dividing line that separated the clinical laboratory from the anatomic pathology lab is becoming blurred.

Because of advances in genetic knowledge and molecular diagnostics, there are now diseases which require close coordination between the clinical laboratory and anatomic pathologists to provide referring clinicians with all the appropriate information needed for diagnosis, to select the appropriate therapies, and to monitor the patient's progress.

Over the past decade, the lab industry has seen some interesting internal politics as, within some hospitals and health systems, the clinical laboratory and the anatomic pathology group would lay claim to a molecular testing program which had been of little interest to either party in its infancy.

In some cases, a turf war for control of molecular diagnostics has led to bitter fights. But more often, the recognition that molecular diagnostics often requires skills and input from both the clinical lab and anatomic pathologists is leading to more integration between the two groups.

As the genetic revolution unfolds, it is expected that all types of specimens can produce information that is helpful to the clinician and his/her patients. That is likely to lead to further integration of clinical lab and anatomic pathology services.

Lab Industry Macro Trend #12

Lab Competitive Bid Project Is A New Medicare Threat

IN A FEW MONTHS, the Medicare demonstration project for competitive bidding of laboratory services is scheduled to commence. If that happens, it will be the realization of a threat that has hung over the lab industry for more than a decade.

"If" is used because the demonstration project is on wobbly legs. It is running behind its announced schedule. As of press time, only sketchy details about the demonstration project have been made public. Those details, announced earlier by officials from the **Centers for Medicare and Medicaid Services** (CMS), have triggered heavy criticism of almost all aspects of the proposed demonstration project.

The initial timetable announced by CMS was to select winning laboratory bidders by January 1, 2007, and launch the demonstration project on April 1, 2007. By the summer of 2006, lack of detail and perceived inaction by CMS officials tasked with implementing the demonstration project caused widespread concern across the laboratory industry.

Politics is likely to play a role in when and how the demonstration project for the competitive bidding of laboratory services takes place. That's because a new Congress was sworn in earlier this month. Both the House and Senate will be under the control of the Democratic Party. It is possible that this change in political control of Congress might lead to changes to the lab competitive bidding demonstration project. That's because new leadership in Congress may not give competitive bidding demonstration projects the same priority as was true of earlier Congresses.

Clients and long-time readers of THE DARK REPORT are familiar with efforts by government healthcare officials in several different programs to rein in the cost of laboratory testing through some type of competitive bidding scheme. During the past 24 to 36 months, both the Florida and California Medicaid programs took steps to institute a restrictive contracting program. In each case, poorly-designed RFPs led to withering criticism and a recognition by the program administrators that the complexity of the programs would make them difficult, if not impossible, to administer successfully.

Similarly, British Columbia's provincial health system had to retreat on a proposed laboratory services contracting scheme. In New Zealand, several district health boards are in the midst of a controversial effort to replace a long-established, reliable laboratory provider with an unproven source that bid a dramatically lower price.

The common theme in these examples is that government healthcare bureaucrats are attempting to cut the costs of lab testing by implementing flawed contracting schemes. Such efforts put the lab industry at risk, not to mention the negative consequences to the healthcare system served by it.

Lab Industry Macro Trend #13

Real-Time QA/QC and Active Search for Lab Best Practices

SEVERAL FORCES ARE AT WORK in the healthcare marketplace which will combine to raise the bar on clinical laboratory quality and laboratory performance.

The common thread linking these forces is the search to identify "laboratory best practices" and use this knowledge to raise the performance of participating laboratories. Across the lab industry, there are laboratory directors and pathologists actively seeking to benchmark their laboratories' performance against that of recognized top-performers.

However, before any laboratory can benchmark itself against another, it must have accurate and relevant information about its own performance. This information must also be in a form that allows it to be compared with the benchmark laboratory in appropriate ways.

This was the impetus behind programs offered through the **College of American Pathologists** (CAP) such as the Laboratory Management Index Program (LMIP) and Q-Probes. These programs began to create uniform sets of data so laboratories could evaluate their own performance relative to that of other labs participating in these programs.

Now the search for useful benchmarks is widening. One interesting development is the effort of several laboratory vendors to create real time QA/QC programs. Examples are the services developed by **Bio-Rad Laboratories, Inc., and Diagnostic Products Corp.** (DPC) that allow participating laboratories to use the Internet to post their lab's QA/QC data and look at peer comparison reports.

Another example is the effort by laboratory and healthcare organizations to study and identify measures which can be used as benchmarks to improve the quality of laboratory testing services and the operational efficiency of clinical laboratories. One such effort is under way at the **Centers for Disease Control and Prevention** (CDC).

In recent months, the CDC created two teams. One team is the Workgroup on Process for Evaluating Best Practices in Laboratory Medicine. The other team is the Workgroup on Proficiency Testing. It is expected that the findings of these teams can be used to initiate improvements in the performance of laboratories across the United States, in an evidence-based manner.

As well, the quality management movement and the use of Six Sigma measurements to evaluate work processes will contribute to benchmarking activities in clinical labs. Expressing the outcome of a work process as errors/defects per million events creates a universal standard of measurement.

In a healthcare system where everything is measured in greater detail and with more speed, laboratory directors and pathologists will need detailed, accurate data to bring their lab to world-class performance.

Lab Industry Macro Trend #14

Evolution in Lab Instruments Will Soon Give Labs New Tools

SEVERAL TECHNOLOGIES are being combined by biotech companies to create a new generation of laboratory instruments. These developing instrument systems have the potential to trigger revolutionary changes in clinical laboratory operations.

The stage was set for this next phase of product evolution by the major *in vitro* diagnostic (IVD) manufacturers. These vendors have developed instrument systems for routine testing that are highly tailored to the needs of a laboratory of any size test volume. It is now possible for a lab of almost any size to buy a highly automated instrument system that has a large on-board test menu, is fully-automated, and integrates effectively with the lab's existing laboratory information system (LIS).

This success has benefited IVD manufacturers and their laboratory customers. The instrument systems used in high-volume core laboratories have helped labs wring out maximum improvements in labor productivity, test quality, and informatics integration.

Now other areas of testing in the clinical laboratory are viewed as opportunities for similar gains in productivity and quality. Along with the major IVD companies, a significant number of biotech firms are working furiously to convert new technology advances into analyzers that can deliver similar quality and operational gains to other sections of clinical laboratory testing.

At least two themes will be common to these efforts. One, the instruments will be designed for simplicity. For example, the operator will need only to load the specimen. The instrument's on-board systems will then perform the appropriate steps required to produce an accurate test result while meeting all regulatory requirements and clinical standards.

That's one goal of products under development at **HandyLab Inc.,** of Ann Arbor, Michigan. The company is working on a miniaturized system for nucleic acid (NAT) testing. It expects to market a hand-held device that uses a lab chip to do specimen prep, DNA amplification, and detection.

The multi-analyte technology developed by **Luminex Corporation** is being used in a range of diagnostic applications. A particularly interesting example is **BioPhysical Corporation** of Austin, Texas. It has created a 250-analyte test panel. Called Biophysical250, it costs $3,400 and provides informed consumers with an evaluation of such conditions as cancer, cardiovascular disease, metabolic disorders, autoimmune disease, viral and bacterial disease, and hormonal imbalance.

These two examples demonstrate how new technology will deliver instrument systems that are likely to change the organizational structure of clinical laboratories. Such instruments will also help laboratories provide more value to clinicians and patients.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It's fast becoming a wireless world in the nation's hospitals. A survey of 300 healthcare executives and upper-level managers published by *Healthcare Informatics* reveals that 72% of those surveyed have a combination of wireless and hardwired systems in their hospitals. Another 5% of those surveyed said their hospitals are already all wireless. This survey indicates the rapid speed with which wireless services are penetrating healthcare.

MORE ON: Wireless Growth

Three out of four healthcare systems that have adopted this technology recognize that wireless access allows clinicians to use handheld and portable devices for data entry. Providers can access data from anywhere, improving productivity. It also allows them to enter patient information and capture charge data at the point of care. Laboratories should be alert to this development and should build the informatics resources necessary to support use of wireless devices.

AMAZING REDUCTION IN ONE CATEGORY OF NOSCOMIAL INFECTIONS

A recent program to reduce nosocomial infections demonstrates the effectiveness of targeted interventions. In Michigan, 103 ICUs (intensive care units) agreed to participate in a study to reduce catheter-related bloodstream infections occuring in ICUs. Evidence-based interventions were used to reduce the incidence of such infections. Results of the study were published last month in the *New England Journal of Medicine* (NEJM). At the start of the program, the median rate was 2.7 infections per 1,000 catheter days. The infection rate dropped to zero at three months! The mean rate per 1,000 catheter days dropped from 7.7 at baseline to 1.4 after 18 months. Researchers disclosed that the analysis included 1,981 ICU-months of data, representing 375,757 catheter-days.

ADD TO: Infection Effort

In a related development, the Missouri Department of Health and Senior Services is now posting selected hospital-acquired infection data on the Internet. The program started on January 4, 2007. Currently the agency posts data on central line-associated bloodstream infections. Later it will report other infection rates. Missouri is one of 15 states requiring hospitals to report infection rates. These two developments are grounded in the patient safety movement. The Michigan program is a demonstration of evidence-based medicine principles carefully put into clinical practice. The Missouri program is an example of transparency in hospital outcomes. The clinical laboratory industry will see similiar initiatives in coming years.

MORE CONSOLIDATION IN RENAL TESTING

Renal Advantage Inc., of Brentwood, Tennessee, acquired **RenaLab** of Jackson, Mississippi, from **Fresenius Medical Care North America** on January 3. Renal Advantage operates 80 dialysis centers in 10 states and is the nation's fourth largest dialysis provider.

That's all the insider intelligence for this report. Look for the next briefing on Monday, January 29, 2007.

Preview #1

Executive War College

May 10-11, 2007 • Intercontinental Hotel • Miami

CASE STUDY: Sunrise Medical Laboratories, Long Island, New York

One of the nation's most successful independent lab companies, Sunrise has something of special interest to all labs across the country. Located on Long Island, in the New York City metropolitan area, it is at ground zero in the battle by the nation's two blood brothers for UnitedHealth business in New York. Learn why Sunrise is competing effectively to capture new physician clients in one of the most intensely-competitive lab markets in the United States. Explore the sales strategies and lab operations projects that have fueled an unbroken chain of annual increases in specimen volume and profits.

For program details, visit darkreport.com

UPCOMING...

- ***National Payer Begins Closing Door to Regional Lab Providers in Southeast U.S.***
- ***How Joint Venture Hospital Laboratories Expanded Its Local Contract with UnitedHealth.***
- ***Operational Excellence: Hospital Lab Achieves World-Class Labor Productivity.***

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