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Special Expanded Issue!

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Our Macro Trends in Clinical Laboratory for 2010!

Understand how market forces are creating new challenges

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

Lab Medicine's Potential Versus Its Challenges

WE ARE STARTING A NEW YEAR. But is it the start of a new decade? That depends on how one decides to determine the first year of a decade. Even *Webster's Dictionary* recognizes this difference of opinion as to the start year of a decade.

For the word "decade," *Webster's Dictionary* offers a definition with two distinctions, as follows. "...2) a period of ten years; esp., in the Gregorian calendar: a) officially a ten-year period beginning with the year 1, as 1921-1930, 1931-1940, etc.; and, b) in common usage, a ten-year period beginning with a year 0, as 1920-1929, 1930-1939, etc." Therefore, Webster's provides cover to advocates of either method for measuring the start and finish of an individual decade.

Having provided you with an argument you can use to defend either method of defining the start of a decade, I'd like to share some thoughts on what lies ahead in laboratory medicine for the years that run from 2010 to 2019 (a decade as defined by "common usage," according to *Webster's*).

First is the opportunity. All of us in laboratory medicine will be part of history's first-ever exploration of the human genome and all the processes associated with the mysteries of life. Science is peeling back the secrets of DNA, RNA, and the human proteome, while at the same time learning practical ways to use this knowledge to heal the sick and improve the health and life of every individual, potentially from the moment of conception to death.

This is an unprecedented opportunity for laboratory medicine. Pathologists and laboratory scientists are poised to contribute immense value to individuals and to society at large. It means that entrepreneurs in lab testing should do well in the coming years by recognizing how to adopt laboratory business models in the new ways necessary to package and deliver valuable diagnostic, therapeutic, and patient-monitoring services to the healthcare system.

On the other hand, the challenge for lab medicine will be how to overturn the resistance to change that is a trait of healthcare in the United States so that the best new genetic science can find its way into clinical diagnostics. It is a challenge built around the adage of "follow the money." Expect the folks getting the money today to resist changes to the status quo which favor rapid adoption of new genetic and molecular testing technologies. Therefore, whether you agree that the new decade starts in 2010 or 2011, what remains true is that the next 10 years have the potential to make pathology a pre-eminent clinical service because of how it delivers life-saving and life-enhancing genetic/molecular information. TDR

New Clinical Lab Trends To Shape Events in 2010

Trends point to more emphasis on excellence in clinical laboratory management and operations

CEO SUMMARY: In presenting this list of macro trends for clinical laboratories, several themes are in play. They range from a continued emphasis on improving lab operations to the need to acquire and deploy sophisticated information technology. During the next few years, the long-predicted retirement of Baby Boomers will kick in. That will aggravate the existing shortage of medical technologists and skilled lab professionals. It is just one of several critical issues soon to challenge lab executives and pathologists.

By Robert L. Michel

IT WAS 2007 WHEN WE LAST PRESENTED a list of current macro trends for clinical laboratory services. This year's list addresses 19 distinct trends, an increase from the 14 clinical lab macro trends we identified at the beginning of 2007.

Now battle-tested for almost a full decade, THE DARK REPORT'S regular review of major trends and developments in the marketplace is a useful strategic planning tool for laboratory executives and pathologists. It provides context for interpreting current developments and describes how the clinical lab testing marketplace is likely to evolve in the immediate future.

2001 was the first year we presented trends and we identified eight. Those eight trends from 2001 are listed on the next page, along with some comments about how each trend influenced the clinical lab marketplace during the balance of the decade.

This is the fifth time since 2001 that THE DARK REPORT has published a list of clinical laboratory trends. It forms a public record of our accuracy in making these predictions. For those interested in studying the forces which shaped the clinical laboratory industry during the years 2001 to 2010, here are the dates of the specific issues of THE DARK REPORT which presented clinical laboratory trends: February 5, 2001; January 20, 2003; January 24, 2005; and January 7, 2007.

One theme has been consistent in each list of clinical laboratory trends. It is the need for labs to perform more testing with less reimbursement. That won't change in 2010.

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Reviewing 2001 Trends For Clinical Laboratories

It was 2001 when we presented our first list of clinical laboratory trends. Here is what we wrote then, and, in italics, our current comments about each trend over the past nine years:

1. CONSUMERS ARE HERE!

In 2001, there was plenty of hoopla about direct access testing (DAT) and consumer activism in healthcare.

For 2010: *A variety of new Internet-based companies sprang up in recent years to serve consumer interest in genetic tests. Similarly, for routine lab tests, a handful of "lab test middlemen" are attempting to reach consumers with a combination of storefront locations and web sites. (See Trend 12, page 16.)*

2. CLINICAL DATA REPOSITORIES.

Efforts to create clinical data repositories were ongoing. Remember CHINs (Community Health Information Networks) from the 1990s? During this decade, the hot term became RHIO (for Regional Health Information Organization).

For 2010: *The term* de jour *is now HIE for Health information Exchange and a handful operate around the country. Given the emphasis on physician adoption of electronic medical record (EMR) systems, we don't see the HIE effort as major trend for clinical labs at this time. (See Trend 6, page 10.)*

3. WEB-BASED LAB TEST REPORTING.

Back in 2001, this was a concept just gaining traction.

For 2010: *In today's market, web-based lab test ordering and reporting is in universal use. The new emphasis is on the LIS-to-EMR interfaces that clinical labs establish with their physicians' office clients. (See Trend 7, page 11.)*

4. LAB REGIONALIZATION.

At least 35 hospital-based regional lab networks were organizing and several examples of multiple healthcare systems forming a single regional lab organization were evidence of this trend.

For 2010: *Instead of an external strategy (regionalization), labs concentrated in internal strategies, particularly in streamlining operations to reduce costs. (See Trend 2, page 6.)*

5. E-HEALTH SERVICES.

2001 marked the decline or failure of many of the first generation of e-health companies (**MedUnite**, **DrKoop.com**, and others).

For 2010: *Now providers use the Internet as a way to expand provider and patient access to relevant health records and information. (See Trend 7, page 11.)*

6. INCREMENTAL AUTOMATION.

THE DARK REPORT is first to pick up increased lab interest for specific automation solutions, such as pre-analytical, workstation consolidation, task-targeted automation.

For 2010: *This trend played out exactly as predicted. (See Trend 4, page 8.)*

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.

For 2010: *This trend also played out exactly as predicted. (See Trends 2 & 3, pages 6 & 7.)*

8. MANAGEMENT PHILOSOPHY.

THE DARK REPORT notes the ISO:9000 certification by **Quest Nichols Institute** and **Kaiser Northwest Lab**, and the launch of **Ortho-Clinical Diagnostics'** Lean/Six Sigma consultancy as first steps toward wider adoption of quality management systems.

For 2010: *This 2001 trend continued through the decade. (See Trend 1, page 5.)*

LAB INDUSTRY **MACRO TREND # 1**

Quality Management Systems Now an Option for Clinical Labs

DURING THE PAST 24 MONTHS, the nation's first clinical laboratories earned accreditation under ISO 15189: Medical Laboratories. This is a noteworthy milestone for the laboratory industry.

ISO 15189 is an internationally-recognized quality management system (QMS). A number of countries around the world now base their requirements for medical laboratory licensure or accreditation on ISO 15189. *(See TDR, October 12, 2009.)*

The fact that a handful of pioneering clinical labs earned accreditation under ISO 15189 in 2008 and 2009—while continuing to meet federal and state licensing and accreditation requirements—indicates the value the leaders of these labs place on implementation of a true QMS within their laboratories. *(See TDR, September 8, 2008.)*

A similar development is unfolding in the hospital industry. In recent years, first movers among the nation's hospitals are earning certification under ISO 9001, a QMS that is used by many industries, including healthcare, around the world. As with clinical laboratories, only a handful of American hospitals have earned their ISO 9001 certification. *(See TDR, June 8, 2009.)*

These developments demonstrate that major healthcare organizations in the United States are recognizing the benefits of adopting a quality management system. It is significant that innovative laboratories are willing to take on the added expense and effort required to successfully introduce a QMS, while at the same time continuing to comply with various federal and state requirements for laboratory accreditation and licensure.

ISO 9001 and ISO 15189 are both comprehensive in how they help an organization design, develop, and deliver a product or service—along with the necessary elements to sustain continual improvement within the organization.

As of this date, **Piedmont Medical Laboratories** of Winchester, Virginia; **Avera McKennan Hospital Laboratories** of Sioux Falls, South Dakota; **Blanchard Valley Hospital Laboratory** of Findlay, Ohio; and the Phoenix, Arizona, laboratory of **Genzyme Corporation** have earned accreditation under ISO 15189: Medical Laboratories.

Each of these laboratories determined that implementation and use of a true QMS would be of ongoing benefit. For starters, many of the major employers in their communities understand the value of ISO and recognize what certification or accreditation signifies.

Because the QMS helps the laboratory continuously reduce and eliminate sources of errors and waste while improving quality, it becomes an effective tool for the laboratory to create added value for its physician clients. In turn, that produces competitive advantage for the laboratory that uses a QMS.

LAB INDUSTRY **MACRO TREND # 2**

More Labs Use Lean Six Sigma To Improve TAT, Performance

WITH EACH PASSING MONTH, additional clinical laboratories, hospitals, and health systems implement their first projects that incorporate Lean and Six Sigma methods.

This broadening acceptance and use of Lean Six Sigma philosophies and techniques continues a trend that started in 2003. That was the year when three prominent health system laboratories implemented the nation's first major Lean projects and reported eye-popping gains.

In their first improvement project focused on the high volume chemistry and hematology lab, each of these three clinical labs cut turnaround time on inpatient testing by 50% or better. The TAT gains were accompanied by increases in labor productivity and cost reductions in the range of 40% to 45%.

In public presentations and published stories, other clinical labs using Lean Six Sigma have affirmed similar outcomes and benefits. This experience is mirrored by those hospitals and health systems which have made a major commitment to using Lean Six Sigma to improve quality, reduce errors and waste, and increase patient satisfaction.

In fact, across the clinical laboratory profession, today the question is less "Should my lab have a Lean Six Sigma program?" and more "When should we launch our lab's first Lean Six Sigma project?" It demonstrates the maturity of this trend, now in its sixth year.

Another factor which reinforces clinical lab adoption and use of Lean and Six Sigma comes from the growing acceptance of these quality improvement methods by most of the leading hospitals and health systems in the United States. At these institutions, the laboratory is often among the first clinical services to implement Lean-based improvement projects.

A further reinforcing trend is the adoption of the ISO 15189 quality management system (QMS) by a handful of first-mover laboratories in the past 24 months. Lean and Six Sigma methods are fully compatible with use of a QMS in laboratory operations. *(See page 5.)*

A key factor in this adoption curve by individual laboratories is the ability of Lean Six Sigma methods to consistently help a laboratory identify the source of errors and waste, then guide its staff to confidently fix those issues. In the case of hospital labs, these methods are particularly effective at helping the lab to cut average test turnaround times in ways that contribute to improved patient care.

One way that this trend will have wider influence in the lab testing industry is its role in contributing to continuous improvement in the quality and delivery of lab testing services. Each time a laboratory uses Lean Six Sigma methods to eliminate a source of waste or add value to the physicians and patients, it contributes to raising the performance bar one notch higher for the entire lab marketplace.

LAB INDUSTRY **MACRO TREND # 3**

Work Flow and Work Processes Become a Management Driver

FEW LAB DIRECTORS AND PATHOLOGISTS recognize this trend. Work flow improvement and work process redesign is, bit by bit, becoming a primary driver in the management and operation of clinical laboratories.

This trend is closely interwoven with the rate of adoption of Lean Six Sigma methods and quality management systems (QMS) by laboratories across the nation. These methods emphasize continuous assessment of work flow and individual work processes and utilize tools and techniques that uncover errors, sources of waste, and other problems—then guide the laboratory's staff in how to fix or improve the performance of the lab's work flow and work processes that were the target of the improvement projects.

Clinical labs are learning that there is another useful benefit from the increased attention given to the evaluation of work flow and the performance of individual work processes. The quality of analytical results is often improved as refinements are made to work flow in the laboratory.

This is true for an obvious reason. It is widely acknowledged that most well-run labs have relatively few errors or problems in the analytical stage. It is the pre-analytical stage where many of the problems that affect analytical quality happen.

Therefore, when a laboratory uses Lean, Six Sigma, and QMS methods to identify the source of errors or waste upstream of the analytical stage, its work flow then delivers better quality specimens to the testing bench.

Over recent decades, many published studies have observed that the analytical stage in most clinical laboratories operates with a high level of quality. The source of the majority of problems in the typical clinical lab tends to be upstream of the testing bench. This includes specimen collection, specimen transport, as well as accessioning, where specimens are prepared for testing.

Modern quality management techniques can be used to identify and fix the sources of errors, to smooth work flow, and to develop standard work practices in such operational activities as collection, transport, and preparation of specimens. Improvements in these areas support increased precision and quality in the analytical stage.

This is why attention to work flow and individual work processes in all areas of the laboratory is becoming an essential complement to the clinical laboratory's traditional focus on the analytical stage. All these parts work together and contribute to increased quality in the diagnostic assays performed by the laboratory.

A widening acknowledgement by laboratory managers about the importance of work flow redesign and process engineering is an affirmation of the usefulness of modern management techniques in helping a laboratory deliver high quality test results.

LAB INDUSTRY **MACRO TREND # 4**

Automation Serves Lab Goals To Improve TAT, Quality, Service

THIS DECADE HAS SEEN an important change in the way laboratories evaluate, purchase, and deploy automation.

When laboratory automation solutions—particularly total laboratory automation (TLA)—were first introduced in the United States during the mid-1990s, these products targeted primarily the high volume chemistry and hematology department of the laboratory.

In these pioneering days for TLA, pathologists and lab administrators generally evaluated automation against two primary criteria. First, would the automation expand the lab's throughput in ways that would: a) allow it to deliver faster average turnaround times; and b) allow it to accommodate a larger volume of specimens without the need to expand the size of the physical space of the lab facility?

The second consideration was how the laboratory automation solution could increase the productivity of labor. This had two benefits.

One, at a time when it was difficult to recruit and retain adequate numbers of skilled medical technologists (MTs) and medical laboratory technicians (MLTs), a TLA installation could test higher volumes of specimens with fewer staff. In turn, this freed up a significant number of MTs and MLTs who could be deployed in other testing departments, easing the manpower squeeze in those areas of the laboratory.

Two, with less labor needed in the automated laboratory, the savings in employee salaries was often a primary source of reduced costs upon which the clinical laboratory's return on investment (ROI) would be calculated.

What a difference a decade makes! Today, TLA is not the primary type of automation available in the market. *In vitro* diagnostics (IVD) manufacturers offer a wide range of automation solutions. It is common to speak of "task-targeted automation," "islands of automation," and workstation/analyzer consolidation, for example.

Automation solutions are available for almost every department in the lab. In recent years, automated products for use in histology, microbiology, and molecular diagnostics arrived in the market, with attractive performance specs and prices.

Those clinical laboratories using Lean, Six Sigma, and similar quality management methods have different motives in purchasing automation today, compared to a decade ago. Now these labs want an automation solution that supports single piece/small batch work flow, reduces variability in work processes, and complements the continuous improvement mindset.

Certainly increased specimen throughput and improved laboratory productivity play important roles in decisions to acquire and deploy today's generation of laboratory automation products. However, these factors must also complement the lab's goals for improved work flow and continuous improvement.

LAB INDUSTRY **MACRO TREND # 5**

Automation Is New Option In Micro, Histology, Molecular

IN MICROBIOLOGY AND HISTOLOGY, there's a "perfect storm" of change underway in long-standing work practices. New automation solutions, when teamed with quality management techniques—such as single piece work flow—are triggering significant improvements in quality and productivity. This is equally true in molecular testing.

Starting around 1995, a steady cascade of new automation solutions began to arrive in chemistry, immunochemistry, and hematology. That was not the case in microbiology and histology. Both of these lab testing areas continued to operate using long-established work flow arrangements based primarily on manual activities.

In recent years, that all began to change. New technologies in several areas gave manufacturers the capability to engineer and build automated systems tailored to specific tasks within the microbiology and histology laboratory. These advances included miniaturized components, more sophisticated information technology, and newly-developed diagnostic technologies that support more precise analysis.

These new technologies have allowed a growing number of *in vitro diagnostics* (IVD) companies to offer some form of automated system for use in microbiology and histology laboratories. In turn, that allows managers in these departments to convert manual work processes to automated work processes.

The disruptive power of these new automated solutions is magnified when the laboratory uses Lean Six Sigma and similar quality management techniques. In such cases, the laboratory can follow the industrial engineer's adage of "don't automate bad work processes." It can use Lean methods to create an optimal work flow, then acquire and deploy the right microbiology or histology automation solution that further increases the productivity and quality of that work flow.

Similar events are unfolding in the molecular laboratory. Each generation of molecular instruments is more automated than the previous generation. Not only does this increase the productivity of molecular labs performing mostly manual assays, but it makes it easier for smaller laboratories and community hospital laboratories to establish in-house molecular testing programs.

Laboratory administrators and pathologists can expect to see ongoing improvements in the range of laboratory automation solutions and their performance capabilities. This will happen in parallel with the development of new technologies at the micro and nano scale. These advances will enable IVD manufacturers to deliver smaller automated systems that have greater capabilities.

The objective will to be identify manual work processes in every area of the clinical laboratory, then provide an automated solution which improves turnaround time, boosts quality and accuracy, reduces errors, and contributes to increased analytical precision.

LAB INDUSTRY **MACRO TREND # 6**

Hospital Lab Outreach Programs Become Service-Rich Offerings

IN THE FINAL TWO YEARS OF THIS DECADE, hospital laboratory outreach programs gained new respect from CEOs and senior administrators at hospitals and health systems across the nation.

This is happening for many reasons. First, as the two national laboratories acquired most of the nation's independent clinical lab companies, hospital administrators noticed the opportunity to provide choice in their local service market.

Second, a well-run, professionally-marketed laboratory outreach program is profitable to the parent hospital or health system. Third, a productive lab outreach program can create substantial capital value for its parent. During the past two years, sales of laboratory outreach businesses by several hospitals have generated tens of millions of dollars for the sellers.

But it is the next two benefits that are catching the attention of strategic-minded administrators at hospitals and health systems. Fourth, a thriving laboratory outreach program builds bridges to office-based physicians that encourage inpatient referrals and more loyalty to the local hospital or health system.

Fifth, first-mover hospitals and health systems have discovered that the laboratory outreach testing program, once it has established client relationships in the community, becomes a highly-valuable channel for selling other hospital/health system outreach services. In particular, a small but growing number of hospitals have begun to package imaging and radiology services with laboratory outreach testing and selling this as an integrated diagnostic service to office-based physicians.

This is an auspicious development for aggressive hospital/health system laboratory outreach programs. By selling a bundled diagnostic service (with lab testing and imaging) to office-based physicians, the lab outreach sales team has a value proposition that larger regional and national laboratories cannot match.

Further, office-based physicians value having electronic access to the full inpatient, outpatient, and outreach record of lab tests and imaging studies for their patients. This can be a source of competitive advantage for a hospital laboratory outreach program.

This nascent trend is likely to have strong legs, for a simple reason. Offering a bundled diagnostic service, with access to the information in a electronic health record (EHR), is an important step forward on the road to integrated patient care.

It reinforces the hospital's mission as a community resource even as office-based physicians gain access to a more complete patient record of diagnostic studies. Collectively, these developments demonstrate how hospital and health system laboratory outreach programs are evolving in ways that add value to physicians and their parent organizations.

LAB INDUSTRY **MACRO TREND # 7**

As Docs Adopt EMRs, Labs Offer E-Prescribing, Imaging Orders

Each time a clinical laboratory establishes an interface between its LIS and the EMR (electronic medical record) system of an office-based physician, it creates a conduit that can serve other functions besides just laboratory test orders and laboratory test results.

Thus, it should not be surprising that enterprising laboratories are actively expanding their LIS-to-EMR interface to include other features which add value for physicians. In the case of **Quest Diagnostics Incorporated**, it introduced e-prescribing in its Care360 product several years ago and says that 150,000 physicians are now connected to Care360

But the most interesting development is how LIS-to-EMR interfaces create a unique opportunity for the laboratory outreach programs of hospitals and health systems. Not only are first mover lab outreach programs integrating e-prescribing within their EMR interface gateway, but they are offering other features which give them competitive advantage.

For example, a surprising number of hospital lab outreach programs have begun to allow physicians to order imaging studies and radiology services from within the EMR, using the LIS-EMR interface. Another feature is to give physicians access to the full electronic health record (EHR) that the hospital or health system maintains on the patient.

Aggressive hospital lab outreach programs say that this gives them a competitive advantage in the marketplace which cannot be matched by their national or regional lab competitors.

The important point here is that any clinical laboratory that builds an LIS-to-EMR interface with an office-based physician has now established an electronic bridgehead within the physicians' EMR that can be used to enable access by that physician to other services and functions. Progressive laboratory organizations recognize that, if they can pack other valuable clinical and operational service features into their LIS-to-EMR interface, it can be a source of competitive advantage for them.

Another factor will reinforce use of the LIS-to-EMR interface in this fashion. Recently-enacted incentives by the federal government to encourage physician adoption of EMRs have vendors scurrying to incorporate "meaningful use" features into their EMR products.

Providers deemed by Medicare and Medicaid to be "meaningful users" of qualified electronic health record (EHR) systems can receive between $40,000 and $60,000 in the form of increased reimbursement during the next five years. The first payment will be based on a provider's "meaningful use" of an EHR in 2011.

Laboratory test ordering is a meaningful use of an EHR. Thus, EHR/EMR vendors and physicians will have a financial motive to work with clinical labs to enable an effective LIS-to-EMR interface.

LAB INDUSTRY **MACRO TREND # 8**

EMR Funding Incentives Open Door to New Compliance Issues

IT'S ALWAYS A MIXED BAG WHEN THE FEDERAL GOVERNMENT wants to steer the healthcare marketplace in a particular direction. That's proving true with recently enacted laws that allow hospitals and other providers to pay up to 85% of the cost of an electronic medical record (EMR) system for an affiliated office-based physician.

The upside is that hospitals, clinical labs, and other types of providers can step up and provide financial assistance to help doctors acquire and implement an EMR system. The downside for the lab industry is that some commercial laboratories and pathology companies take an expansive interpretation of these revised laws.

It was 2006 when federal lawmakers changed laws and rules that limited hospital financial support for physician implementation of EMRs. Revisions were made to the Anti-Kickback Statute and the Stark Physician Referral law to create new safe harbors and exceptions to the regulations. One year later, in 2007, the Internal Revenue Service made a favorable ruling that allowed not-for-profit hospitals to donate EMR systems and related support services to affiliated doctors.

Responding to these changes to the law, some lab companies found ways to provide substantial financial assistance to selected client physicians for EMR acquisition and implementation using arrangements that a number of laboratory compliance experts believe to be in violation of the recently rewritten federal laws and regulations.

By their willingness to stretch the compliance boundaries pertaining to EMR donations in their favor, these commercial labs and pathology firms are able to dangle a financially-lucrative EMR donation package to existing and new physician clients that will not be matched by competing laboratories with a more conservative compliance policy.

Because physicians often do not pay close attention to the nuances of Medicare anti-kickback laws and Stark self-referral legislation, they are all too happy to take the richer EMR donation package. In turn, that rewards those commercial labs and pathology companies willing to push compliance in this matter to the extreme.

True to form, federal healthcare enforcers are reluctant to publish detailed guidance about which situations it considers to be in violation and which are not. The consequence is familiar to those laboratories which follow a conservative interpretation of these laws and regulations.

The conservative labs regularly lose important customers and business to a handful of competing lab companies that are willing to subsidize the physicians' purchase of an EMR system with lavish financing and assistance arrangements that the conservative labs' attorneys consider to be in violation of the compliance requirements for EMR donations.

LAB INDUSTRY **MACRO TREND # 9**

Middleware Comes into Its Own And Gives Labs Extra Function

IN THE PAST 24 MONTHS, middleware has come into its own as a product line and solution for clinical laboratories. Many clinical laboratories now consider middleware to be an accepted and useful complement to the laboratory information system (LIS).

This is a positive development for the laboratory industry. It means a major change to the longstanding business model of reliance on a "do it all" LIS to handle the complete information technology needs of a clinical laboratory.

In that business model, the lab generally needed to rely on the LIS vendor to write custom code to enable different functions and features. That process often took a long time and cost plenty of money, since the LIS vendor might not have the programmers available to spend time on projects relevant to only one customer.

Today, laboratories can engage any number of middleware companies to help them develop customized capabilities that meet their needs. These middleware sources are often faster and cheaper than the LIS vendor at implementing effective solutions.

Two factors underpin this evolution in how laboratories work with information technologies (IT). First, as laboratories become more sophisticated in how they manage work flow, they need a variety of IT solutions to track—in real time—the progress of specimens through the lab, monitor the performance of analyzers and automated systems, and identify problems in the laboratory as they occur.

Second, the rapid pace of innovation in the IT field has created new solutions for laboratory managers. Computer hardware is continually improved so that it can handle larger volumes of data with increased speed. The newest generations of software are more robust, simpler to program, and easier to interface with other IT systems.

Just as ongoing improvements to the personal computer and its connection to the Internet give the user more capabilities and more reliability at less cost, similar changes are unfolding in the "big iron" world of computing. Clinical laboratories directly benefit from these ongoing improvements.

Middleware solutions give laboratories a way to handle a myriad of issues that happen between the analyzers and the LIS. For example, middleware is what allows laboratories to use rule-based decision processing (also called expert systems) to manage a wide range of activities in the laboratory. This might involve autoverification of results, as well as the real-time monitoring of analytical systems and the flow of specimens through the laboratory.

For laboratories that are combining Lean Six Sigma and lab automation, middleware is often the perfect complement to optimize the lab's use of these tools.

LAB INDUSTRY **MACRO TREND # 10**

SaaS and Cloud Computing Gaining Acceptance by Labs

TWO GOOD EXAMPLES of how information technology (IT) is transforming the way clinical laboratories use new technology are the business models of "Software as a Service" (SaaS) and cloud computing.

Let's start with definitions, courtesy of *www.wikipedia.com*. First, SaaS: "Software as a service (SaaS, typically pronounced 'sass') is a model of software deployment whereby a provider licenses an application to customers for use as a service on demand. SaaS software vendors may host the application on their own web servers or download the application to the consumer device, disabling it after use or after the on-demand contract expires."

Second, cloud computing: "Cloud computing is Internet- ('cloud-') based development and use of computer technology ('computing'). In concept, it is a paradigm shift whereby details are abstracted from the users who no longer need knowledge of, expertise in, or control over the technology infrastructure 'in the cloud' that supports them.

"Cloud computing describes a new supplement, consumption and delivery model for IT services based on the Internet, and it typically involves the provision of dynamically scalable and often virtualized resources as a service over the Internet... Typical cloud computing providers deliver common business applications online which are accessed from a web browser, while the software and data are stored on servers."

Laboratory managers and pathologists are encouraged to become more familiar with the concepts of SaaS and cloud computing. Experts predict that these two information technology business models will be disruptive to the long-standing practice of a company owning both the software and the hardware.

Each new IT model can deliver substantial savings and operational benefits compared to the more familiar business model where the laboratory buys the laboratory information system (LIS) software and the hardware required to run it, then pays to maintain both.

Instead, in the world of SaaS and cloud computing, the laboratory essentially rents what it needs and lets the vendor maintain the systems. This outsourcing arrangement means the laboratory no longer has to carry the capital cost of acquiring hardware and software, along with staffing an information technology (IT) department to operate the systems.

During the past five years, a number of the nation's larger laboratory organizations have adopted SaaS solutions for such important functions as billing and collections. Other laboratories have decided to move their LIS to a cloud computing arrangement.

To date, there have been no public disclosures of major service disruptions caused by these arrangements. That's a positive sign that SaaS and cloud computing are robust solutions and ready for prime time use by clinical laboratories.

LAB INDUSTRY **MACRO TREND # 11**

Molecular Testing Contributes Ever More Clinical Value

MOLECULAR DIAGNOSTICS is now an integral part of laboratory medicine. Almost every clinical laboratory in this country offers some type of molecular assay on their test menu. This is a dramatic change from 1999, the last year of the last decade.

The rapid acceptance of molecular diagnostics can be seen in infectious disease testing. Since 2000, the clinical market for infectious disease testing has seen a steady flow of new molecular assays.

In general, for a new molecular infectious disease test to be successful, it must: 1) offer a faster time to answer; 2) have an acceptable level of sensitivity and specificity compared to current lab test options; and 3) have a competitive cost relative to other test options. Certainly it is the ability of a rapid molecular test to deliver a clinically useful answer in hours that supports expanded screening for MRSA infections at hospitals throughout the country.

One important development in the field of molecular diagnostics is the arrival of new automated systems into the marketplace. Automating assays and methods that formerly had to be done manually makes it possible for more community hospital laboratories to establish in-house molecular testing programs.

Going forward, three parallel technology development curves will expand the role of molecular diagnostics in clinical laboratories. The first technology curve involves continual advances in molecular technologies that lead to new types of assays that speed up time to answer and provide more sensitive and specific results in cost-effective ways.

The second technology curve involves continual improvements to automated, self-contained testing systems. These will be "load and walk away" and will make it easier for labs with smaller volumes to maintain an in-house molecular testing program.

The third technology curve will be the use of different specimen types for molecular testing. Published studies are demonstrating the viability of saliva and human breath as valid specimens for molecular testing. For cancer tests, molecular assays are already available that use blood, not tissue, for the specimen.

The ongoing and parallel development of these three technology areas points to a rosy future for expanded molecular testing in the clinical laboratory. Pathologists and laboratory administrators will want to keep their strategic options open to benefit from these developments.

Finally, one more disruptive factor should not be overlooked. Experts now believe that the race to the $1,000 whole human genome sequence may end within 24 months—and might produce an automated system that can sequence a whole human genome for $100.

Don't be surprised if a vendor then creates an automated instrument that allows a community hospital lab to produce an accurate whole human genome at this price. That would be a true molecular game-changer!

LAB INDUSTRY **MACRO TREND # 12**

Consumers Step Up Interest In Ordering Their Lab Tests

CONSUMERS ARE PAYING evermore attention to laboratory tests. At the same time, there is no clear business model that clinical labs can use to serve this heightened consumer interest.

Direct access testing (DAT) is on the radar screen of growing numbers of consumers. But few laboratories have yet figured out the perfect business model to serve this consumer market. Over the past decade, any number of clinical laboratories established DAT programs. They often used their patient service centers and/or local pharmacies as the place where consumers could come and conduct business with them.

In most cases, consumers did not transact enough business for routine laboratory tests, such as chemistry panels, CBCs, and lipid panels, to justify the lab's costs to support a DAT program.

However, even as these attempts to establish a financially sustainable DAT program fizzled, consumer interest in laboratory testing increased steadily throughout the decade. This opportunity did not go unnoticed outside the laboratory testing profession.

To serve this market, a number of lab testing companies were created—often by entrepreneurs with little or no formal training in laboratory medicine. These companies were organized around one goal: to give consumers a way to order their own laboratory tests.

These companies see their mission as marketing directly to consumers. Most do not perform their own testing, but contract with an established clinical laboratory to perform testing. **Anylabtestnow.com** and **Healthcheckusa.com** are examples of this emerging business model focused on consumers.

Similarly, genetic testing marketed to consumers is a growth industry on the Internet. There are a number of companies in this sector. Examples include **DNA Direct**, **23andMe**, and **Navigenics**.

Meanwhile, consumers are driving demand for selected tests at established clinical labs. Take the example of Vitamin D testing. In recent years, a regular flow of media stories has educated the American public about the widespread incidence of Vitamin D insufficiency. And don't forget the impact that Oprah Winfrey can have when she discusses lab tests like Vitamin D with Dr. Oz, her favorite doctor.

Thus, it should not be a surprise that the volume of Vitamin D tests performed in the United States has skyrocketed during the past 48 months. Consumers and their physicians are responding to the public information about the importance of adequate levels of Vitamin D.

What these developments indicate is that, in keeping with experts' predictions, consumer interest in lab testing is a growing phenomenon. It's just that the lab testing industry has yet to develop the best business model to serve consumers who want to order their own laboratory tests.

LAB INDUSTRY **MACRO TREND # 13**

Home Brew Testing Grows, As Does FDA Intent to Regulate

AS A TREND, the growth in laboratory-developed tests (LDTs) has been a headline topic in recent years.

Also known as home brew tests, laboratory-developed tests are being used more frequently by clinical laboratories as a way to offer proprietary diagnostic tests to the clinical marketplace. These developments caught the attention of the **Food and Drug Administration** (FDA) in recent years.

The FDA first signaled its serious intent to increase its regulation of LDTs when, in 2006, it published draft guidance on *in vitro* diagnostic multivariate index assays (IVDMIA). Since then, there has been ongoing public debate over increased FDA oversight of laboratory-developed tests.

At the end of last year, Steven Gutman, M.D., who was preparing to retire from his position as Director of FDA's Office of *In Vitro* Diagnostic Device Evaluation and Safety, stated: "I have no doubt that some of these lab-developed tests are very high in quality. I also have no doubt that some of them are not so high in quality. What I don't know is... whether tests of less value will in fact produce a branding issue that might come back to haunt labs. If poor quality tests enter the market, then people could lose confidence in tests more generally."

To date, a few skirmishes between the FDA and the diagnostic industry show how the regulatory agency is looking for opportunities to demonstrate its authority and set policy. For example, during 2008, **Laboratory Corporation of America** introduced a laboratory test called OvaSure. This test had been developed at **Yale University** and was advertised as useful in detecting early stage ovarian cancer.

The FDA responded to this development with two letters demanding that LabCorp cease offering the OvaSure test. The FDA stated that LabCorp did not qualify for the LDT exemption because: 1) the test was developed at Yale University, not at LabCorp; and 2) the test utilizes materials not manufactured by LabCorp. LabCorp objected, but it did pull the OvaSure test from the market. *(See TDR, October 20, 2008.)*

One financial firm estimates that as many as 70 LDTs have been commercialized as proprietary tests. One of the earliest and most successful companies that pursued this strategy is **Myriad Genetics, Inc.**, of Salt Lake City, Utah. Its introduction and market development of its predictive genetic test for breast cancer—BRACAnalysis—has become a business model copied by other companies with proprietary test technology.

The longer the FDA delays action on the home brew issue, the more complex the problem will become. That's because, as the market activity involving LDTs increases, any regulatory action taken by the FDA will be more disruptive—both for labs offering home brew tests, as well as the physicians ordering those tests.

LAB INDUSTRY **MACRO TREND # 14**

Patient Satisfaction Surveys Raise Competitive Bar

BY REQUIRING HOSPITALS to survey patient satisfaction, accrediting bodies like **The Joint Commission** (TJC) have raised the profile of hospital laboratories in ways that were both unimagined and unexpected.

Phlebotomy is a great example of how patient satisfaction surveys can change long-standing management practices in hospitals and health systems. Prior to the emphasis on patient satisfaction surveys, few senior administrators in hospitals and health systems paid much attention to phlebotomy services in their hospital.

That changed in a rather dramatic way in recent years. Phlebotomy is now an actionable source of patient satisfaction improvement, watched closely by many hospital/health system CEOs. This is without precedent in modern lab medicine, since the laboratory was generally off the administrative radar screen unless there was a problem that affected patient care or other areas of the hospital.

How did phlebotomy become an item of interest to hospital CEOs? The answer is directly linked to patient satisfaction surveys. The surveys used by most hospitals typically ask questions about 10 clinical and operational services within the institution. Often the laboratory ranks at the bottom of the list, at number 9 or 10.

Accreditation requirements now call for the institution, once it has measured patient satisfaction, to raise those scores by the next accreditation cycle. Thus, when the hospital CEO asks why the laboratory is at the bottom of the list, they quickly learn a fact of life well-known to laboratory professionals.

That fact of life is that a significant and large number of patients don't like needle sticks. Some even have a phobia of needles. Thus, patient satisfaction scores relating to the laboratory confirm that fact, since the only experience many hospital patients typically have with the laboratory is with phlebotomy and specimen collection.

How can a hospital CEO lift the patient satisfaction score of the laboratory? He can improve the phlebotomy experience of the patient. That is a reason why some hospital CEOs have authorized spending money on phlebotomy products that make the experience of blood collection more patient-friendly.

What this increased attention on patient satisfaction with phlebotomy and specimen collection demonstrates is that patient satisfaction surveys can be a trigger and guide that helps hospitals and clinical laboratories improve. More importantly, this improvement occurs to services and products that are important to the patient.

This is consistent with one major point that quality guru W. Edwards Deming always stressed: the only meaningful definition of quality is that which the consumer specifies.

LAB INDUSTRY **MACRO TREND # 15**

Clinical Labs Get Creative To Maintain Med Tech Staff Levels

IT IS WIDELY RECOGNIZED that the supply and skills of Medical Technologists (MTs), Medical Laboratory Technicians (MLTs), and other laboratory scientists will not be adequate to meet the expanding needs of laboratories.

This skilled labor squeeze occurs for two primary reasons. The first reason is the existing absolute shortage of skilled laboratory professionals that already exists in many regional markets and certain areas of laboratory science. The second reason is the demand for the advanced (and often different scientific) skills required to work with new diagnostic technologies.

Increased specialization across the range of activities in laboratory medicine is another factor that exacerbates the market for skilled laboratory expertise. Yet, many academic programs still teach mostly the traditional basics of laboratory science.

It is common for new technologies and science in laboratory medicine to outpace the ability of academic programs to incorporate this new knowledge into their course content. That creates an education burden on laboratories hiring graduates from these programs, since the lab recognizes it must provide training in the specialized area of laboratory testing where the new hire will work.

Alert readers recognize that these factors in the demand/supply equation for skilled laboratory scientists are independent of another widely-recognized issue: the looming retirement of baby-boomers. Put these three factors together and the immediate prospects for an adequate supply of skilled laboratory professionals become discouraging.

Despite these circumstances, innovative clinical labs are proactively attacking the problem of a tight market in skilled laboratory professionals. One strategy is to become more efficient with lab operations and work flow.

Thus, use of Lean, Six Sigma, and similar quality management methods can streamline work processes and improve productivity. That frees up MTs who can be assigned to other areas of the laboratory. Use of automation to increase productivity is a complementary strategy that many labs find beneficial.

Distance learning is another strategy gaining favor as a way to maintain adequate lab staff. It allows a laboratory in any smaller city or community to help existing and newly-hired employees complete the academic studies and degrees required for them to handle more complex duties in the laboratory. Academic programs across the nation that offer distance learning programs in laboratory science reported steady increases in enrollment over the course of this decade.

Despite these strategies, until the training pipeline ramps up to accommodate larger numbers of students, most clinical labs will find it increasingly difficult to maintain authorized levels of laboratory professionals.

LAB INDUSTRY **MACRO TREND # 16**

Point-of-Care Testing Poised To Make Bigger Contributions

POINT-OF-CARE TESTING (POCT) may be the most overlooked area of diagnostic technology development. But rapid changes in this sector of laboratory testing guarantee a larger role for POCT in coming years.

Today's point-of-care testing products are improving at a swift pace. This is true for both the instrument systems used to perform the analysis, as well as the diagnostic technology used to evaluate the specimen. In a step-wise fashion, vendors are making these POC devices clinically and operationally more robust.

At the same time, market acceptance of POCT products is strong, as reflected in year-to-year sales increases. POCT sales are growing at double digit rates annually, compared to single digit rates for routine chemistry and hematology testing systems.

What may surprise pathologists and laboratory administrators is the POCT segment posting the fastest growth. It is the patient self-test segment. Research firm **Espicom Healthcare Intelligence** issued a report on point-of-care diagnostics and stated that the worldwide market for POCT in 2008 was valued at $12.6 billion and grew 11%.

It says that patient self-testing represents $8.9 billion, or about 71% of the total POC market. Espicom also indicates that the growth rate of consumer POCT outstrips the growth rate of POCT in what it terms the "professional care sector"—physicians' offices, hospitals, and other types of health providers.

Highest-growth segments include POC cardiac markers, hospital POC glucose testing, coagulation self-testing, and home cholesterol and drugs-of-abuse testing. In 2008, for patients with chronic atrial fibrillation and venous thromboembolism, Medicare approved coverage for at-home blood testing of prothrombin time (PT) and International Normalized Ratio (INR).

There is another aspect of POCT which shouldn't be overlooked. Intense efforts are ongoing to create POCT solutions appropriate to the needs of underdeveloped countries. These tests will be used in settings where healthcare resources are meager and electricity is often unavailable.

However, as these systems demonstrate their ability to provide a reliable clinical answer at an attractive low cost, some eager entrepreneur is going to adapt them for use in developed countries. Because these POC tests will produce a clinically reliable result at a cheaper cost, they are likely to be tough competitors for existing test methodologies available in developed countries.

In the forseeable future, use of point-of-care testing will continue to grow. For that reason, forward-looking clinical laboratories will want to develop an effective strategy to help manage POCT within the communities and regions that they serve.

LAB INDUSTRY **MACRO TREND # 17**

Multi-Modality Diagnosis Makes Early Progress

HERE IS A TREND THAT IS STILL IN ITS INFANCY. Innovators in several sectors of healthcare are taking the first steps to introduce multi-modality diagnosis into clinical use.

The concept here is to pull together all the relevant clinical information and patient history, then guide the physician to the right answer. One obvious starting point to achieve a multi-modality diagnostic capability is to combine laboratory test data and imaging studies.

The growing role of tumor boards in bringing together all the clinicians involved in caring for a patient is one example of how pathologists and radiologists are becoming involved in more collaborative activities affecting patient care. Tumor boards can be seen as one step on this road to multi-modality diagnosis.

Another approach to multi-modality diagnosis is for pathologists and radiologists to interact more regularly. Currently, only in a handful of sites in the United States does a radiologist and a pathologist regularly sit down side-by-side and review the primary images each uses to evaluate a patient. Their common goal is to improve concordance in their respective findings in ways that directly improve the accuracy of the primary diagnosis and the information provided to the referring physicians.

This diagnostic collaboration is likely to become more commonplace as clinical service silos are broken down and replaced by integrated care models. Advances in healthcare informatics will be another factor that contributes to increased integration of clinical care and greater use of multi-modality diagnosis.

One credible effort to use the power of information technology as a way to enable multi-modality diagnosis is at the **Laboratory for Computational Imaging and Bioinformatics (LCIB), Rutgers University** in Piscataway, New Jersey. Informaticians there are making impressive progress.

LCIB Director Anant Madabhushi, Ph.D., describes the vision as "multi-modal, multi-scale, multi-functional computer aided detection (CAD) to improve cancer diagnosis, prognosis, and theranosis." His team is incorporating histology information—including images and cancer grading—with magnetic resonance spectroscopy, functional magnetic resonance imaging, bioinformatics, and image analysis tools.

These researchers want to use information technology to bring together all the relevant clinical information for a patient, then use sophisticated software to evaluate this information against evidence-based medicine (EBM) standards to guide the physician to a more accurate diagnosis, as well as the most appropriate therapeutic options.

Multi-modality diagnosis is a trend that requires labs to work more collaboratively with other clinicians. It is consistent with healthcare's evolution toward an integrated service.

LAB INDUSTRY **MACRO TREND # 18**

Many Local Labs Still Access Managed Care Contracts

DESPITE YEARS OF EXCLUSIONARY CONTRACTING EFFORTS by the nation's largest health insurance corporations, many local laboratories still have access to managed care patients in their service area.

This was not the popular wisdom back in 2007. Early that year, **UnitedHealth Group, Inc.**, initiated an exclusive 10-year national lab testing agreement with **Laboratory Corporation of America** while excluding **Quest Diagnostics Incorporated** as a national provider. During 2007, **Aetna, Inc.**, signed an exclusive national contract with Quest Diagnostics and it excluded LabCorp as a national provider.

Based on these events, some lab industry experts believed that the major health insurance companies were about to become more effective at excluding local laboratories as network providers. Moreover, there were predictions that the major managed care companies, as they implemented these restrictive exclusive national contracts with one or both of the two blood brothers, would significantly reduce leakage (testing done by out-of-network laboratories).

Now, 36 months later, regional and local laboratories still have much the same access to managed care patients that they did back at the start of 2007. Market indications are that national health insurers continue to recognize the benefits of local access and enhanced services that many regional and local laboratories provide in the communities that they serve.

Assuming that, collectively, local labs still have much the same level of access to managed care patients at the end of 2009 that they did at the start of 2007, this may be a sign of how much value local labs deliver to physicians and patients in the communities they serve.

After all, the major managed care companies and the two national lab companies that offer them deeply-discounted pricing, have a strong economic motive—and considerable marketing resources—to convince physicians to stop using their local laboratory provider and instead use the national lab(s) that hold the exclusive contract for that payer.

The fact that these powerful corporate players did not move market share as they planned during the past 36 months would indicate that local physicians are quite loyal to the community laboratory that serves them. It validates the high-touch service strategy conducted by most of these local and regional clinical laboratories.

If there is a next threat in the managed care contracting arena, it may be the need for local laboratories to provide managed care companies with more sophisticated information technology services. Payers are now asking laboratories to provide more detailed clinical, operational, and financial data. This gives local labs, particularly hospital lab outreach programs, the opportunity to add value by feeding enriched data sets to payers.

LAB INDUSTRY **MACRO TREND # 19**

Underfunding for Lab Testing Can Undermine Quality

TODAY, THE UNITED STATES enjoys a clinical laboratory testing service that is considered one of the best in the world.

At the same time, the nation's payers, both government and private, have continually nibbled away at the level of reimbursement paid for laboratory testing services. That means the day approaches when the amount of money paid to reimburse clinical laboratories will be inadequate to cover the fully-loaded cost of providing testing services.

Current efforts to enact a sweeping healthcare reform bill in Congress continue the trend of eating away at laboratory reimbursement. The projected cutbacks in laboratory funding are substantial, representing reductions of between 6% and 9% over the coming 10 years.

The **American Clinical Laboratory Association** (ACLA) describes the proposals in the House and Senate versions of the bill thusly:

Summary (figures approximate): The House bill applies a productivity adjustment that would reduce the [Medicare Part A] Clinical Laboratory Fee Schedule (CLFS) by $7.35 billion over ten years, or 6% of total Medicare spending on lab services. The Senate bill applies a productivity adjustment differently which saves an estimated $5 billion, with an additional $5 billion reduction for a total savings of $10 billion or 9% of total Medicare spending on lab services.

These proposed cutbacks in laboratory funding must be seen in context. For 10 of the past 12 years, Congress has voted not to fund an update (increase) to the Clinical Laboratory Fee Schedule based on the Consumer Price Index (CPI). On top of that, the CLFS is already scheduled to be reduced 1.9%, effective January 2010.

What compounds the effect of these reductions to the Medicare fee schedules for laboratory testing is that private health insurance companies commonly base their own laboratory reimbursement on the Medicare fee schedule. Thus, anytime the Medicare Clinical Laboratory Fee Schedule is reduced, private payers attempt to implement similar reimbursement reductions with laboratories contracted in their provider networks.

From across the globe, there are warning signs about the consequences of sustained underfunding for laboratory testing services. THE DARK REPORT has alerted the laboratory profession to quality problems as they have become public in countries ranging from Canada to Ireland and New Zealand.

Invariably, inadequate funding is one element identified as a contributing cause to the failures in lab testing programs that become public knowledge in these countries. These episodes should serve as a warning to health policymakers and elected officials in the United States.

It is foolish thinking to starve the budget for an irreplaceable clinical service that, for about 3¢ on the dollar, is the source of accurate diagnostic and therapeutic knowledge. **TDR**

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