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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Is Healthcare Undergoing a Fundamental Shift?

ONE OF THE MOST DIFFICULT RESPONSIBILITIES in laboratory management is deciding when to implement substantial change. Pathologists and lab administrators correctly understand that there are risks for acting too soon or too late when responding to changes in the healthcare marketplace.

That's why this year's list of key trends in anatomic pathology is particularly interesting. Collectively, these trends indicate that deep structural changes may be the end result of the current change cycle in the American healthcare system.

I believe this to be true because we seem to be at a crossroads. The last healthcare change cycle began with the advent of the Medicare program in 1966. Medicare is a "command and control" business model. It dictates clinical service requirements and reimbursement levels using techniques disconnected from market economics. With the passage of federal legislation creating health maintenance organizations (HMOs) in 1974, "command and control" came to the private health insurance industry, eventually leading to the gatekeeper-model HMOs of the last decade.

In my view, the past 40 years was a cycle where attempts to control the year-to-year increase in healthcare costs were dominated by "rule makers," whether in the Medicare/Medicaid programs or the private health insurance sector. Few pathologists or lab directors would disagree that this approach to managing the nation's healthcare system has failed to meet most of its major goals: quality of service, relatively easy access by most of the population, and good value for the quality of healthcare delivered. Everyone agrees that the system in the United States doesn't work as well as it needs to. It's the disagreement about how to fix healthcare's problems that triggers controversy and intense emotions.

That is why I pose this question. Could the American healthcare system be entering a new cycle of change—but this time oriented towards putting the consumer in charge of his or her healthcare? This may be true because employers, having learned the lessons of quality management, understand that it is the expectations of customers that define quality. From that premise, a consumer-driven healthcare system should outperform the "command and control" system that has failed us in so many ways. TDR

Anatomic Path Trends Portend Deep Changes

Structural changes in healthcare will require strategic responses from pathology groups

By Robert L. Michel

CEO SUMMARY: Our biannual review of trends shaping the anatomic pathology profession reveals that a wide range of influences are active. The nation's healthcare system is undergoing fundamental changes in how it views the quality of health services and how it will favor top-performing providers. For pathology group practices, this list of eight trends should be incorporated in strategic planning efforts.

ON THE SURFACE, IT SEEMS LIKE A quiet time for the anatomic pathology profession. Unlike the tumultuous years of the 1990s, there is no single force pushing rapid change upon the nation's pathology groups.

However, a careful reading of the eight anatomic pathology trends presented in this issue of THE DARK REPORT reveals that deep structural changes are occurring to the American healthcare system. As a consequence, the anatomic pathology profession is on the leading edge of the next evolutionary cycle. It is a cycle that will eventually bring about a radical restructuring of the form and delivery of anatomic pathology services.

It will take several years for these changes to work their way through the healthcare system. For that reason, the direct impact in the short term will be fairly minimal. But over the long term, these changes promise to change the foundation of the American healthcare system, thus requiring the anatomic pathology profession to change as well.

There are two key drivers to watch. First is the patient safety movement. Employers, payers, and government health programs are using patient safety as a goal to effect a new mindset among physicians and healthcare administrators. The objective is to instill an awareness that: 1) patient safety can and should be measured; and 2) that every provider has a responsibility to continuously improve patient safety.

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2001's AP Trends Reveal Change in Market

BELOW ARE THE SIX key anatomic pathology trends published in THE DARK REPORT in January 2002. The older list, when compared with the key trends of 2004, shows how factors outside the anatomic pathology profession now exert the strongest pressures.

1. Influence of national anatomic pathology firms
2. Consumers find pathology
3. Pathology centers of excellence
4. First signs of genetic and molecular pathology
5. Internet and telepathology create new opportunities
6. Shortage of pathologists and technologists

The second key driver is the trend to measure provider performance and use that information to allow consumers to select better-performing hospitals and physicians. Again, employers and government health programs are supporting this change. They believe it will lead to higher quality care at a lower cost.

Two New Objectives

The important thing to understand about these two trends is that they represent an effort to create a fundamental change within the American healthcare system. Employers, government health programs, and private payers want hospitals, physicians, and other types of providers to incorporate both goals into the daily routine. Goal one is to measure patient safety and improve it continuously. Sustained effort is to be directed at eliminating the source of medical errors.

Goal two is to measure healthcare outcomes with increasing accuracy. As with patient safety, providers are to continuously work to improve outcomes. In both cases, accurate and detailed measurement data will be collected and reported.

New Management Mindset

For hospitals and physicians to achieve these goals, it will require a different management mindset and new management tools. The same holds true for pathology group practices and clinical laboratories.

The remaining key anatomic pathology trends listed on the following pages relate more directly to technologies and developments that are closely linked to the anatomic pathology profession. These trends will unfold in parallel with the patient safety movement and the effort to measure providers' outcomes and rank them.

Collectively, I predict these trends will be slower-acting than many of the healthcare trends of the 1990s. The 1990s was a time of sustained reductions in reimbursement, lots of consolidation among providers, and battles to gain access to managed care patients. By the end of the decade, most pathology group practices continued to operate from the common business model used throughout the 1970s and 1980s.

By the end of this decade, I believe the trends now under way will reshape the form and structure of pathology group practices in new ways. That's because of the emphasis on reducing medical errors and measuring outcomes, in tandem with coming generations of automation in the histology laboratory, new insights on how to use quality management systems to drive outcomes, and the general trend toward an all-digital patient medical record. Further, pathology may actually lead some of the genetic revolution.

Key Trend 1:

Patient Safety & Provider Outcomes

CONSIDER PATIENT SAFETY and the measurement of provider outcomes as opposing edges to the same sword.

Wield the sword in either direction, and it cuts in an identical manner. To improve patient safety, it is necessary to measure and evaluate the performance of providers. To measure provider outcomes with the goal of identifying those providers doing a better job than their peers, the same data measurements are required.

Laboratory administrators and pathologists can already see the influence of both trends. During 2002 and 2003, THE DARK REPORT has regularly provided intelligence and analysis about each trend.

For pathology group practices, patient safety and measurement of provider outcomes will change many traditional customs in the overall practice of medicine. For example, in past years, the medical profession has fought hard to keep private the disciplinary actions taken against physicians by state medical boards.

Similarly, there has been reluctance to make information about medical malpractice settlements easily available to the public. In this same vein, the medical profession has generally opposed the collection and publication of information pertaining to the performance of individual physicians.

This is ending, even more rapidly than THE DARK REPORT expected. Pathologists will see these changes by watching two areas. First is the measurement and public ranking of hospital performance. Medicare already has an evaluation program under way with approximately 1,700 hospitals. In a two-year period, those hospitals which show improvement in the several clinical services being measured will see additional reimbursement. Those hospitals with declining performance will see a reduction in reimbursement.

The second area to watch is the private health insurance industry. Health plans are establishing programs which pay financial incentives to physician groups which achieve higher outcomes. Examples can already be found in California and New York. *(See TDR, June 16, 2003.)* In the Northeast, **Aetna, Inc.** has established a health plan in which it only allows top-performing physicians and hospitals to participate.

What is common in the hospital and physician projects mentioned above is a careful measurement of selected performance indicators. Initially, there are financial rewards attached to better performance. Subsequently, the performance rankings of hospitals and physicians will be made public and will be used to determine which providers can participate in the networks established by private payers, Medicare, and Medicaid.

Although this will impact pathology groups in several ways, at a minimum, it will increase the motivation of hospitals and referring physicians to more intensely use anatomic pathology services which contribute to improved patient outcomes. Those pathology groups which can demonstrate that capability will gain competitive advantage over their peers.

Key Trend 2:

Move to Consumer-Driven Healthcare

CONSUMERS ARE REGAINING power in the American healthcare system as a direct result of support by employers and the current administration.

This will lead to changes in the traditional relationships laboratories maintain with consumers. To date, this has mostly been through the patient's physician. However, the structural changes occurring to the design of health plans, combined with the heightened interest of consumers in taking a more active role in their healthcare, will increasingly bring the consumer into direct contact with the laboratory or pathology group providing diagnostic services.

Employers are taking the lead role in this development. First, employers are chastened by their role in supporting closed-panel, gatekeeper-model HMOs during the past decade. To avoid the appearance that their health plans constrain employee access to care, employers are now designing health plans which allow employees to make greater choices.

Second, employers have been hit with double-digit increases in their healthcare costs for four consecutive years. To reduce the year-to-year impact of this trend, employers are structuring health benefit plans in several ways. One approach is to increase deductibles and out-of-pocket payment requirements. Another approach is to fund "flexible" spending accounts and let the consumer make all the decisions on the first few thousand dollars of annual healthcare spending.

Congress is playing a role in this trend. The recently-enacted Medicare bill has two components which will encourage greater consumer participation. One, the bill authorizes the expansion of private Medicare health plans. Two, the bill authorizes a major enlargement in the potential use of medical savings accounts (MSAs).

Collectively, efforts by employers and this administration are reinforcing consumers' interest in having full access to care and selecting the physicians and hospitals they prefer. It means that consumers will make the decisions on how to spend their healthcare dollars—not their employers and not their insurance companies.

THE DARK REPORT has already noted that a growing number of consumers are calling pathologists directly to discuss their biopsy results. The early efforts to establish direct access testing programs (DAT) by clinical laboratories are well known. These are signs that the there is active movement toward consumer-driven healthcare.

Pathology group practices face an interesting professional dilemma. As a hospital-based practice, most pathology groups have had easy access to inpatient and outpatient specimens. It was not necessary to maintain marketing and sales to sustain an adequate flow of specimens.

However, the twin trends of consumer choice and the ability of office-based physicians to treat more types of cancers and other diseases may mean that hospital-based pathology groups must develop a strategy to capture specimens which originate outside the hospital or health system.

Key Trend 3:

Six Sigma/Lean Arrive In Path Labs

EARLY-ADOPTER PATHOLOGY LABS are involved in the first-ever projects to redesign histology laboratories and pathology operations from the management methods known as Six Sigma and Lean.

It is too early to report the outcomes from these projects. That's because the first major efforts to apply these quality management principles to a major overhaul of the design and workflow of large histology laboratories are underway even as you read these words.

However, the expectation is that these projects will deliver sizeable gains in quality, productivity, turnaround time, and cost savings. As revealed in THE DARK REPORT earlier this year, the first three large hospital laboratory organizations to redesign their high-volume core chemistry and hematology laboratories saw improvements of up to 50% across the board in turnaround time, error reduction, productivity, and quality. *(See TDR, September 8, 2003.)*

It is the magnitude of these gains which deserves notice. There is no precedent for a 16-week lab management project to generate a 50% reduction in average turnaround time for routine inpatient tests—in laboratory organizations that are already considered well-managed by various benchmarking measures! Moreover, this 50% reduction occurred even as labor inputs were reduced by 50% and quality measures similarly improved.

Among the first group of hospital laboratories to apply Six Sigma and Lean in a high-volume core laboratory setting were **DSI Laboratories, Inc.** of Fort Myers, Florida, **Fairview Health Services** in Minneapolis, Minnesota, and **West Tennessee Healthcare** in Jackson, Tennessee. Encouraged by the successes of their first Six Sigma and Lean project, each of these lab organizations has moved to a second phase.

In the second phase, Six Sigma and Lean projects have been initiated in other hospital labs within the health system, as well as in at least one histology laboratory. Expectations are application of Six Sigma and Lean methods in histology laboratory work flow redesign will generate comparable gains to those seen in the high-volume core laboratory projects.

THE DARK REPORT is first to point out that the pathology profession will not be able to ignore the types of performance gains posted by laboratories diligently applying the quality management methods first developed by W. Edwards Deming, Joseph Juran, and others.

At a time when healthcare is squeezing reimbursement for laboratories, asking for a reduction in errors, and measuring the quality of services, no pathology group practice can afford to ignore these types of management tools. The outcomes from these first histology laboratory makeovers, once they become known, will most likely establish new performance benchmarks for the nation's most progressive laboratories.

What is uncertain is how fast the quality principles used in these management systems become adopted on a widespread basis.

Key Trend 4:

National Market for AP Services

IT'S TIME TO FORMALLY RECOGNIZE that an established national market for anatomic pathology services now exists.

Thanks to the many thousands of sales calls made to office-based physicians by sales reps from such companies as **DIANON Systems, Inc.**, **Urocor Inc.**, **IMPATH, Inc.**, and others during the 1990s, a sizeable number of physicians are now in the habit of referring their anatomic pathology (AP) specimens to national AP companies.

This national market is far from mature. It will continue to develop and display new characteristics as more clinicians become comfortable with the concept of sending their anatomic pathology specimens to laboratories not located in their immediate community.

For local pathology group practices, this is a trend which should not be ignored. A substantial number of office-based physicians are now comfortable collecting tissue and sending it to an anatomic pathology laboratory that may be located thousands of miles away. Local pathology groups no longer have an automatic "birthright" that entitles them to get specimens originating in nearby physicians' offices.

Certainly the anatomic pathology companies listed above have had their business problems. But different national anatomic pathology companies are being created to capitalize on the national market for anatomic pathology specimens.

This means that local pathology group practices need to rethink their long-term and short-term business strategies. It is no longer a safe decision to concentrate on inpatient work and avoid investments in building the sales and marketing infrastructure required to properly develop and service specimens from office-based physicians.

That's because many cancers and other diseases can now be treated in physicians' offices and other non-hospital settings. If a pathology group practice does not pursue these outpatient and outreach specimens, it will find itself losing market share. As a smaller percentage of patients are treated in the hospital, any local pathology group practice that limits itself only to inpatient services will find it tougher and tougher to generate the revenues needed to acquire new technology and sustain pathologist incomes.

The existence of a national market for anatomic pathology services also changes a fundamental premise in the business plan of most local pathology group practices. During the 1980s and 1990s, they had the good fortune to be in a business that gave them a near monopoly on specimens in their immediate medical campuses. This meant that such groups did not have to invest in marketing, sales, enhanced customer services, and similar business functions.

This situation has changed with the arrival of national anatomic pathology companies. To compete effectively over the long term, local pathology group practices will need to become less like a hospital-based physician group and more like a stand-alone business enterprise.

Key Trend 5:

Molecular Pathology on the Increase

MOLECULAR PATHOLOGY IS on the ascendency. Today, testing that utilizes some form of molecular technology represents only a tiny fraction of the total volume of work done by anatomic pathologists. But that is changing fast.

During the past two years, advances in genetic science have reached the point where announcements of new molecular-based assays are made monthly. It's true that the majority of these new assays have limited clinical application and offer incremental improvements over existing methodologies.

But the regular flow of such new molecular-based assays into today's healthcare market is an important sign of the huge research effort underway worldwide. This research will continue to deliver ever-growing numbers of new assays into the clinical marketplace.

Tumor markers are the hot ticket in this diagnostic segment. For a growing number of cancers and diseases, the standard of care is expanding to incorporate molecular-based tests in conjunction with the traditional slide-based evaluation of cell morphology.

This requires anatomic pathologists to shift their personal practice habits and include molecular diagnostics into their care protocols. As this happens, an interesting turf battle is emerging in laboratory organizations across the United States.

Until recent years, most molecular labs were launched by a champion within the laboratory who was willing to fight a variety of battles to cadge funding for instruments, to collaborate with specialists on developing useful diagnostic assays, and to acquire knowledge about molecular diagnostics using the "learn by doing" approach.

In the early years of such labs, no one cared much about who was responsible for them. Some molecular laboratories were operated within the pathology department and some were operated under the clinical laboratory department.

However, as molecular assays play a greater role in a growing number of cancer types and other diseases, there is real power attached to whoever controls these once-fledgling molecular labs. That fact has made the existing molecular laboratory in many hospitals and health systems the point of contention between clinical pathologists and anatomic pathologists.

Who will win this battle? It really doesn't matter. The battle itself illustrates an important point: the historical points of differentiation between the clinical laboratory and the anatomic pathology laboratory are starting to crumble.

Laboratory medicine based on genomics and proteomics is going to require an integrated laboratory service organization. Traditional roles defined by clinical pathology and anatomic pathology are going to evolve into new, as yet undetermined forms.

The important insight to glean from the advances in molecular pathology is that the form and shape of clinical and pathology laboratories that we have known to date are already evolving. Successful labs and pathology groups will recognize this fact and actively accept the need to evolve in parallel with these changes.

Key Trend 6:

"Real Time" AP Is Approaching

REVISED CLINICAL GUIDELINES for a variety of diseases and conditions are requiring a faster time to diagnosis.

At the same time, new diagnostic technologies are making it faster and faster to perform a test and report the results. There are numerous examples of this in the clinical laboratory. Anatomic pathology is about to undergo similar pressures to reduce average times required to report results.

In the clinical laboratory, one good example of the need to compress time to results is cardiology. New guidelines for emergency room (ER) treatment specify that, once a cardiac patient arrives at the ER, the attending physician should start, as appropriate, medication within 30 minutes or have the patient in the cath lab within 45 minutes.

In these situations, ER physicians and clinical pathologists are exploring ways to speed up the turnaround time for lab tests done for these patients. Solutions include point-of-care testing and rapid response labs in the ER. The latter solution was implemented at **Massachusetts General Hospital** in Boston in recent years.

The same pressures for faster results now pushing clinical laboratories will soon be seen in anatomic pathology laboratories. As physicians are more closely measured on the outcomes they achieve for their patients, they will want to use those laboratories which help them achieve better outcomes. Thus, the changing expectations of physicians will be one force for improving turnaround time in the anatomic pathology laboratory.

A model for this new type of anatomic pathology is emerging in Miami, Florida. Azorides Morales, M.D., using brand-new technology and instrument systems, has created what might be called point-of-care-anatomic pathology at the **University of Miami/Jackson Hospital**.

Dr. Morales has constructed a histology laboratory next to the oncology ward of the hospital, near the surgical suites. Using new instrument systems, this histology laboratory and the pathologists stationed there are able to deliver a diagnosis to physicians even as the patient is wheeled out of the recovery room!

Dr. Morales will be at the *Executive War College* on April 27-28, 2004 to share the details of this "real time" pathology effort. The instrument system he is using will soon be available for purchase. He reports that his histology laboratory now allows pathologists to sign out 70% of their cases by 5:00 p.m. the same day the specimen was received.

This is one example of how the drive towards "real time anatomic pathology" may become a reality. It becomes technically feasible as a new generation of automation reaches histology laboratories. But the expectations of physicians, payers, and patients are equally important. It is their desire to get results ever faster that will push anatomic pathology groups.

There is good evidence that the anatomic pathology profession may be on the verge of achieving "real time results. Such a situation was unthinkable just a few years ago!

Key Trend 7:

Recognized Shortage of Paths & Techs

MANY SIGNS POINT to a perceptible shortage of pathologists in the marketplace. That reverses the situation of the last decade, when concerns about an oversupply of physicians were prevalent.

Physician recruiters and other experts tell THE DARK REPORT that there is a strong demand for pathologists with subspecialty skills in today's healthcare marketplace. *(See TDR, November 10, 2003.)* This should not be surprising. Inpatient admissions climbed steadily in recent years, increasing the volume of specimens to be tested. These same years have also seen a steady flow of new diagnostic tests enter the healthcare marketplace.

Even as work for pathologists is expanding and stimulating demand for more subspecialty skills, anatomic pathology laboratories face a severe challenge in finding enough histotechnologists. Nationwide, the shortage of histotechs is already acute. During site visits to laboratories throughout the country, THE DARK REPORT is consistently told by these labs that they are already unable to hire sufficient histotechs to handle the existing volume of specimens moving through their pathology laboratory. Most laboratories report having authorized histotech positions which go unfilled because of a lack of qualified candidates.

Taken together, the available supply of pathologists and histotechnologists is already falling short of existing demand. This means that anatomic pathology laboratories will face a double bind during the years to come. First, they will struggle to recruit, train, and retain an adequate number of histotechnologists for their laboratory. Second, effort will be required to recruit pathologists with the right mix of subspecialty skills needed to match that laboratory's unique mix of patients.

Certainly the market forces of supply and demand are already at work to address this imbalance. Medical schools are expected to expand enrollment. Compensation for histotechs is starting to rise and additional training programs are under development.

Meanwhile, automation of work processes in the anatomic pathology laboratory is under way. Such automation reduces the need for labor, allowing trained professionals to devote their skills to higher, value-added tasks.

During the next 24 months, there will be lots of news about how the redesign of histology laboratories using quality management methods like ISO, Six Sigma, and Lean, in combination with new automated instrument systems, are reducing the labor hours required to process and diagnose anatomic pathology specimens.

Some of the earliest examples of histology lab "makeovers" will be reported at the upcoming *Executive War College on Lab and Pathology Management* in New Orleans on April 27-28, 2004. Additional intelligence on the supply-demand situation for anatomic pathologists will appear on these pages during 2004.

Key Trend 8:

Age of the Pathologist Subspecialist

PATHOLOGY SUBSPECIALIZATION has been around for a long time. What has changed is the scale of the demand for pathologists with subspecialty skills.

There are at least three main factors which feed the demand for pathologist subspecialists. First, both referring physicians and their patients are showing an increased willingness to search out pathologists with nationally-recognized skills and have these pathologists review their cases.

Second, many of the new, sophisticated diagnostic procedures reaching clinical use require a pathologist to have specific technical knowledge and experience. As diagnostic tools multiply for specific diseases, the pathologists specializing in these diseases must keep current with the standard of practice. This not only encourages specialization within anatomic pathology, but makes it increasingly difficult for the generalist pathologist to maintain state-of-the-art competency across all major diseases.

Third, the national commercial laboratories have a voracious appetite for pathologists with specific subspecialties. Physician recruiter Richard Cornell of **Integro Medical, LLC**, based in St. Louis Missouri, estimates that commercial laboratory companies may already employ as much as 10% of the nation's board-certified pathologists. *(See TDR, November 10, 2003.)*

There's another factor that further encourages subspecialization within the anatomic pathology profession. That is the legal risk from malpractice claims. As the plaintiff's bar becomes more familiar with new diagnostic technology, it is expected that malpractice actions will include a new legal strategy. That strategy will be to claim that, unless a pathologist-subspecialist diagnosed the plaintiff's case, proper standard of care was denied to the plaintiff.

Is the day of the generalist pathologist approaching its end? Certainly not! In many hospital settings around the United States, generalist pathologists will play an essential role. This is particularly true of smaller hospitals and hospitals located in rural communities.

What will probably be different is the number of cases referred by generalist pathologists. As the barriers to effective telepathology fall (because of better technology, elimination of regulatory barriers, and change in practice referral patterns), generalist pathologists may become more like a quarterback for cases requiring subspecialty review.

In these instances, the generalist pathologist must coordinate all the pathology services required and insure that both referring physician and patient get a timely and accurate response on each case referral.

Interestingly, the same technologies and cultural shifts which encourage more pathologist-subspecialists may also benefit pathologists who want to practice in the small hospital. While maintaining their generalist duties, they can also develop subspecialty expertise and review cases presented to them via the Internet. It may prove to be a "best of both worlds" outcome for the anatomic pathology profession. TDR

Offering Molecular Tests Has Surprises & Pitfalls

Labs face financial risk if payers and clinicians are slow to accept new molecular-based tests

CEO SUMMARY: Laboratories that offer some of the new assays based on molecular technologies often find themselves facing significant financial risk. That's because payers are skeptical about new lab tests which come at a high price, but don't offer substantial clinical benefit. One early-adopter laboratory shares advice about how to identify, in advance, some of the surprises and pitfalls that accompany these tests.

DIAGNOSTIC TEST KITS FOR ASSAYS based on molecular technologies are now pushing their way into the marketplace. However, most payers have yet to fully accept many of these tests and establish adequate reimbursement for them.

Additionally, lab directors at several early-adopter laboratories tell THE DARK REPORT that the introduction of new molecular-based assays triggers a variety of problems, each of which can generate significant financial risk if not handled promptly and effectively.

One Lab's Experience

One laboratory which has plenty of experience in evaluating and introducing new molecular-based assays is **NorDx Laboratories** of Scarborough, Maine. Its President and CEO, Stan Schofield, has relevant insights into the management problems—and solutions—for handling the challenges of offering new molecular technologies to clinicians.

"Our laboratory is open to all new technologies," stated Schofield. "We want to be proactive in helping bring new diagnostic assays to our clinicians. For that reason, we have seriously evaluated many of the new molecular-based kits as they enter the marketplace.

"One conclusion from our experience so far is that there is considerable finanical risk in setting up a new test before there is wide acceptance of the test by both payers and clinicians, and before adequate reimbursement is established," observed Schofield. "This makes it prudent for a laboratory to evaluate several factors before making the decision to offer a molecular-based test."

"Further, cost pressures on the healthcare system mean that payers are exercising great caution and taking extra time when making decisions to cover new tests and setting reimbursement levels. This environment challenges diagnostic manufacturers, because widespread acceptance by payers and ample reimbursement sometimes takes years to achieve," noted Schofield.

"This is why there is financial risk for laboratories which may be too quick to acquire and set up some of these new molecular test kits," he continued. "Labs can lose a lot of money until such time as payers and clinicians know enough about these types of new assays to accept them and pay adequate amounts for them."

Schofield has five relevant examples that illustrate the types of issues laboratory administrators and pathologists need to identify and track prior to making a decision to offer new molecular-based assays. Each is based on the experience of specific molecular assays which have reached the laboratory marketplace Each illustrates the confusion that results when tests are "approved" for clinical use, but payers establish different types of reimbursement criteria. Unsuspecting laboratories often learn about these problems only after payers return claims with a "denied" stamp on them.

Non-Coverage By Payers

Issue one is non-coverage by payers. "Labs need to be aware that payers may simply refuse to cover a new assay based on molecular technology," observed Schofield. "A great illustration of this is the decision of **Trailblazer Health**, which is a Medicare Part B carrier for Maryland, Delaware, Virginia, Washington, D.C., and Texas. It announced, about two years ago, that it would refuse to cover 34 tests which used amplified probes and similar technologies.

"Under pressure from a variety of laboratory professional organizations, Trailblazer Health has agreed to cover seven of these tests, effective October 1, 2003. But we've not seen that change yet. And we have a local payer in Maine which has used the decision of this particular Medicare carrier to refuse coverage for some of these tests."

Issue two currently challenges both molecular test kit vendors and their laboratory customers. It's the payer's oftenlengthy process of updating existing diagnostic methodology. "The molecular version of the fecal occult blood test is a good example of this problem," he explained. "Medicare's existing reimbursement was $4.54. This was updated to $18.56 with the new CPT code.

Inadequate Reimbursement

"That seems like a generous reimbursement update," said Schofield. "However, it proves to be less than half of the reimbursement level necessary for the molecular version of this test to be be economically viable for both vendor and laboratory.

"Let me explain," continued Schofield. "**Enterix Corp.**, located here in Maine, offers its In-Sure™ test, which can be reimbursed by Medicare at the $18.54 rate. However, Enterix has said in a recent newspaper article that it must sell its test kit (to laboratories) at a minimum of $28.00 to generate enough revenue to stay in business. Next, the laboratory must add its direct costs and overhead to the kit price. This pushes the total reimbursement needed closer to $40.00 if both laboratory and diagnostic vendor are to recover their cost of offering this test.

Lab Can Lose Money

"NorDx has found a number of molecular tests where this type of reimbursement gap exists," observed Schofield. "It puts the lab in the position of losing money each time it performs one of these tests and fails to generate enough reimbursement to recover the full cost of performing that test."

Issue three arises when a payer takes the lab's claim for a molecular test billed at its proper CPT code and cross-walks it to another CPT code used by the older, non-molecular methodology. "In these instances, the older methodology is

reimbursed at, say, $3 or $4 dollars per test," said Schofield. "When called, the payer says 'why should we pay your lab up to ten times more for the same test result, just because you used a new technology?' In such cases, a laboratory can be stuck paying $18 for a molecular test kit, with only a $4 reimbursement to offset its costs."

"...labs should verify reimbursement policies independent of the representations of their diagnostic vendor," he advised. "Sales reps have been known to stretch the facts if it helps them complete a sale."

Issue four involves gaps between Medicare's reimbursement policies for screening tests and how a physician orders certain tests. "**Abbott's** UroVision™ bladder cancer marker illustrates this principle," stated Schofield. "Just as was previously the case with PSA testing, Medicare will not pay for this bladder cancer test if it is a screening test. The laboratory must educate physicians about this type of molecular assay and use ABNs appropriately. Otherwise, claims for this test will be denied.

"Not only should laboratories be aware of this type of acceptance criteria, but labs should verify reimbursement policies independent of the representations of their diagnostic vendor," he advised. "Sales reps have been known to stretch the facts if it helps them complete a sale. Once the contract is signed, however, it is the laboratory that must live with the downstream consequences."

Issue five involves the lag in clinical practice acceptance after payers have established specific reimbursement criteria. "The changes in cervical cancer screening make a great illustration of this point," observed Schofield. "Recent changes in clinical guidelines call for DNA-based HPV testing in patients meeting specific criteria. As well, a three-year cervical cancer screening cycle is now appropriate for some patients.

"The good news is that payers have accepted these guidelines. **Aetna** is reimbursing **Digene's** DNA with Pap® test at $58. But Aetna is strict in vetting every claim to verify that the reimbursement criteria have been met," stated Schofield.

"For laboratories, this creates pressure in several ways," he explained. "First, the vendor can be aggressive in encouraging the laboratory to set up and offer the test, even though few clinicians are ready to accept and order the new test. Second, the laboratory must devote considerable resources to helping physicians shift their clinical practices to the new recommended guidelines.

Need To Educate Patients

"Third, patients need to be educated. In the case of cervical cancer screening, both HPV testing and a three-year interval (for women meeting specific clinical criteria) are new recommendations. Women need to learn why cervical cancer screening procedures are changing and accept these new guidelines. Fourth, as noted above, payers are reimbursing for these tests only if very specific criteria are met," stated Schofield.

These examples demonstrate why labs need to consider a range of issues before deciding to purchase, set up, and offer new molecular-based assays. On the following pages, Schofield shares some advice on how laboratories should negotiate contracts with vendors for these types of tests. TDR

Contact Stan Schofield at 207-885-7888.

RFP Secrets To Use When Buying Molecular Tests

NorDX Labs considers its vendor contracts to be critical when introducing new molecular tests

CEO SUMMARY: It often takes two to four years before payer coverage and reimbursement become stable. During that time, NorDx Laboratories wants the vendors who sell it new molecular assays to have some "skin in the game." It accomplishes this by negotiating contracts that link the contract's renewal to NorDx's success in getting both payers and physicians to understand and accept the molecular test.

PAYERS AND PHYSICIANS NO LONGER rush to accept every new diagnostic test entering the marketplace. For that reason, laboratories must have a strategy to address the best time and circumstances for acquiring and offering new assays based on molecular technologies.

At **NorDx Laboratories** of Scarborough, Maine, that strategy can be described as "buy right and make the vendor a partner" in the laboratory's success with the new assays it acquires. "We developed this management strategy out of necessity," stated Stan Schofield, President and CEO of NorDx.

"Our laboratory needs to offer clinicians the latest in new diagnostic tests, but we cannot afford to lose money on these tests," he said. "Yet, payers are slow to cover these tests. Reimbursement is frequently insufficient to fully cover our costs for these tests. For these reasons, it is logical that our best partner in developing a new test is the vendor which manufactures it."

However, Schofield's laboratory is careful to do its homework before it even launches contract negotiations with a diagnostic manufacturer. "Look before you leap!" he advised. "Once your lab signs a contract to acquire these tests and offer them, it must live with downstream financial consequences if payers either resist accepting these tests or fail to reimburse an adequate amount.

Evaluate Payers and Docs

"A financially successful molecular testing program starts with more than just a careful evaluation of the diagnostic technology itself," continued Schofield. "Before entering into vendor contracts, two important constituencies should be evaluated.

"First, meet with your lab's important payers. In advance of launching the new test, you need to know whether they will cover this test, how much they intend to reimburse for the test, and what type of educational support they will need to make positive decisions on both points," he said.

"Second, determine how physicians in your area will react to the availability of the molecular-based test you intend to introduce," advised Schofield. "One good place to start is to meet with key clinical leaders in your lab's service area. What if they react poorly to the science behind the test or its use in clinical settings? You need to be forewarned about what types of objections you may have to overcome to successfully introduce a new molecular-based assay.

"Physician education is critical if any new laboratory test is to be accepted," he added. "This is particularly true of many new tests based on molecular technologies. Before most physicians will change practice patterns and order new lab tests, they need to learn about the clinical studies and documentation which support the use of those new diagnostic tests.

"NorDx has learned that these first two steps need to be done before any contract is signed with a diagnostic manufacturer," added Schofield. "Because we've done our homework, we can negotiate terms which meet the needs of physicians in our region and best reflect the speed with which major payers are expected to accept these molecular-based assays."

Molecular Revolution

"At this point in the molecular revolution, NorDx finds itself dealing with most or all of these issues with every new diagnostic test that incorporates new molecular technology," he said. "For that reason, we've learned valuable lessons about how to evaluate these new tests. It's helped us to develop a customized implementation program for our laboratory. The goal is to maximize our ability to offer clinicians these tests and bill for enough reimbursement to fully recover our costs to provide such tests.

"When it comes to negotiating a contract for new molecular-based lab tests, our laboratory has learned three key lessons," noted Schofield. "These reflect my opening admonition of 'look before you leap!' NorDx only starts negotiations after it has done its homework. It takes lots of time and resources to do this right. And because management resources are limited, at times, it can be frustrating.

"Lesson number one is that the vendor contract has as much to do with the clinical and financial success of the molecular-based tests covered by that contract as any other factor."

"Lesson number one is that the vendor contract has as much to do with the clinical and financial success of the molecular-based tests covered by that contract as any other factor," he declared. "For that reason, NorDx is a tough negotiator and has several requirements.

"First, NorDx does not enter contracts that are fixed term or open-ended. Rather, our contracts are structured to 'renew' based on reimbursement changes and clinical acceptance. The contract defines these factors in ways that are relevant to our laboratory," explained Schofield."Second, our contracts include clauses that allow us to put the vendor on notice about these key issues. We have a mutual 90-day 'out' clause.

"Our contract philosophy is that the vendor should partner with NorDx on these new molecular tests," he added. "Clauses such as the two mentioned above force the vendor to pay attention to changes in coverage crite-

ria and reimbursement. We understand that the reimbursement situation today for new diagnostic tests is often fluid and unstable. It may take two to four years after the introduction of these new tests before they achieve a stable level of reimbursement.

Sharing In Financial Risk

"That's one reason why we want our vendor to be as closely tied to coverage criteria and reimbursement as we are," he continued. "They have experience and resources to lobby payers in ways that NorDx doesn't. Most importantly, it helps protect our laboratory from downstream financial losses if payers and clinicians fail to embrace the new test.

"The second key lesson we've learned involves balancing the needs of the patient and the physician with the economics of reimbursement," said Schofield. "The NorDx implementation strategy specifically includes clinicians. This process is becoming more complicated for laboratories than ever before. We find that we must introduce every new assay to each physician in a unique way that relates its clinical benefits to that physician's practice. Fortunately, physicians are beginning to understand these new parameters.

Key Lesson Number Three

"Key lesson number three is to do a full cost analysis *before* buying a new test," advised Schofield. "We don't take anyone's word on this point—neither vendor nor payer. In particular, don't ever let the vendor do the cost analysis for your laboratory and then rely on that cost analysis in your purchase decision.

"NorDx always does its own analysis," he said. "The first time or two it can be time-consuming. But our management team now has an accurate template, developed with the help of our financial experts. The assessment of costs we do now is invariably more accurate than any done by outside sources.

"Key lesson number four is always, always, *always* create a competitive bidding situation among competing vendors," stated Schofield. "Frequently there are enough vendors offering similar assays that we can invite more than one to respond to our RFP (request for proposal).

"In fact, my favorite adage around here is 'competitive bidding is a laboratory manager's best friend!' Competitive bidding has helped NorDx avoid many of the downstream financial burdens that result from poorly-crafted vendor contracts. We may be a tough negotiator at contract time, but the resulting agreement creates a better ongoing working relationship with the successful vendors," declared Schofield.

Minimizing Finanical Risk

The experience of NorDx Laboratories demonstrates why the introduction of new molecular assays continues to be a financially high-risk decision for many laboratories. This is particularly true if the new molecular assay only makes a modest clinical improvement over existing methodologies. That is why NorDx decided the best strategy was to negotiate contracts with vendors that made them "partners" in the clinical and financial success of the tests they manufacture. TDR

Contact Stan Schofield at 207-885-7888.

Stan Schofield to Speak at Executive War College

Stan Schofield will be at the *Executive War College* in New Orleans on April 27-28, 2004 to speak further about establishing a profitable molecular diagnostic testing program and negotiating effective vendor contracts.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There's a new joint venture between a commercial laboratory and a multi-hospital group. On January 5, 2004, **Lab*One*, Inc.** of Lenexa, Kansas announced that it had completed negotiations with **The Health Alliance of Greater Cincinnati**. Lab*One* paid $38.5 million to acquire core laboratory assets of the hospital-owned venture. It will also manage the rapid response labs in six hospitals and provide reference testing. Lab*One* intends to build a new core laboratory during 2004 and expects to keep most existing testing in Cincinnati.

MORE ON: LabOne

Several aspects of this new joint venture are noteworthy. First, this is a major expansion for LabOne and the first time it has demonstrated its willingness to participate with hospitals in this type of laboratory venture. Second, the price paid by LabOne demonstrates that hospital laboratory outreach programs have capital value, in addition to the other benefits they provide to the parent hospitals.

EMEGENCY ROOMS BECOMING SOURCE OF PRIMARY CARE

Here's interesting confirmation that ever-increasing numbers of people are using hospital emergency rooms as their source for primary care. Use of emergency rooms in Tennessee is up by more than a third since 2000. The **Tennessee Hospital Association** (THA) issued an astonishing report. For the fiscal year ending June 30, 2003, 2.9 million people visited emergency rooms. This was an increase of 4.1% from the previous year, and a 34.6% increase from 2000. During fiscal 2003, emergency room visits by indigent and self-pay patients increased 20.1%. For patients in **TennCare**, the state's Medicaid program, emergency room visits have increased by almost half, 49.1% in the three-year period of 2000-03.

ADD TO: ER Visits

Among other reasons, a poor economy and higher unemployment in Tenessee is one explanation as to why visits to the emergency room are increasing so rapidly. But another reason seems to be Medicaid reimbursement levels which many physicians consider to be inadequate. "When TennCare patients cannot find doctors willing to see them or take care of them in a timely manner, they have little choice but to turn to hospitals who do not turn patients away," stated Craig Becker, President and CEO of THA. Tennessee's experience demonstrates how a continual squeeze on reimbursement discourages provider participation. It also indicates that hospital laboratories may continue to see growing numbers of indigent and self-pay patients showing up in emergency rooms seeking primary care, not emergency care.

• In Oakland, California, there's a new laboratory start-up that has just launched clinical testing services. **Machaon Diagnostics, Inc.** is offering coagulation testing. Michael P. Ero is its President.

• Pathology has lost another of its prime contributors. At the end of December, Kenneth McClatchey, M.D. died of cancer. Long-affiliated with **Loyola Medical Center** in Chicago, he had been Editor of *Archives of Laboratory Medicine*.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, February 2, 2004

PREVIEW #2

EXECUTIVE WAR COLLEGE

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Case Study–Confessions of a Sinner: "I Automated Bad Work Processes in My Lab"

It's one of the most remarkable lab stories of recent years. The consolidated core laboratory at West Tennessee Healthcare in Jackson, Tennessee recently installed a state-of-the-art automated laboratory. Within a year, it then launched a major Six Sigma/Lean makeover of its high-volume core laboratory. Learn how lab management came to realize that automation had delivered only a fraction of the lab's potential productivity and that it could achieve greater gains with less automation.

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