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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

Why Can't Hospital Laboratories Collaborate?

MOST PEOPLE KNOWLEDGEABLE ABOUT THE INNER WORKINGS of the clinical laboratory industry generally agree that hospital laboratories possess inherent advantages over commercial laboratories—anytime a hospital lab outreach program is organized properly and marketed professionally.

Certainly the managed care contracting success of **Joint Venture Hospital Laboratories** (JVHL) in Detroit and throughout the state of Michigan bears testimony to the potential of hospital laboratories to operate competitive outreach programs against the national commercial laboratories. *(See pages 2-5.)* Since its founding in 1992, JVHL has outlasted public lab companies such as **Universal Standard Medical Laboratories** and **SmithKline Beecham Clinical Laboratories** while helping its member hospital laboratories expand their share of the physicians' office marketplace in Greater Detroit.

This achievement required a level of unity and commitment by participating hospital lab directors that is seldom seen around the country. From the chosen business structure of its regional laboratory network to close teamwork in developing the type of lab data reporting formats requested by payers, JVHL demonstrates how collaboration between hospital labs can be to everyone's benefit.

So why is it that other regional laboratory networks around the United States have found it so difficult to organize around an economically-sustainable business model and then build outreach lab testing business from physicians' offices in their community? Maybe an equally valid question is to ask, if Detroit's hospital labs could work so effectively together and compete successfully against the two blood brothers, why have the pathology groups that anchor these hospital labs failed to organize an equally effective "regional pathology network"? It certainly seems that a pathology network layered on top of JVHL's clinical laboratory network would have the inside track to chase national pathology companies like **DIANON Systems** and **IMPATH** out of the Detroit market.

Of course, there are predictable answers to these questions. Efforts to create collaboration between different hospital labs are frequently stymied because lab directors can't get past issues of control or long-standing competitive feelings about their cross-town brethren. That's a shame, because a little collaboration could take these hospital laboratories a long way in their home town. TDR

Michigan Lab Network Wins Major HMO Deal

Latest contract award comes at the expense of one of the national commercial lab firms

CEO SUMMARY: By winning the contract for Health Alliance Plan (HAP), Joint Venture Hospital Laboratories (JVHL) captured another major exclusive managed care contract for lab testing services in Southeast Michigan. Its victory demonstrates that local hospital lab outreach programs can compete on equal terms with national laboratory competitors. Service and enhanced lab data reporting are keystones to its success.

THERE'S BIG NEWS in the city of Detroit. On May 1, 2002, **Joint Venture Hospital Laboratories** (JVHL) becomes the exclusive provider of laboratory testing services for **Health Alliance Plan** (HAP), a 125,000-member HMO.

"Becoming the exclusive laboratory for HAP is a major milestone for our regional laboratory network," stated Jack Shaw, JVHL's Executive Director. "Our lab network now holds provider status with every major HMO in this region! JVHL services lab testing contracts that cover 1.35 million people."

JVHL's accomplishment is remarkable. It is the first regional laboratory network in the nation to achieve provider status with every major managed care plan in its service area. It is all the more remarkable because of another fact: JVHL competed on equal terms against the national labs. It bested them in contract awards because of the potential ace card that all hospital labs can play—it is a locally-based laboratory services organization that provides testing services that users acknowledge to be better than those offered by competing labs, including the two blood brothers.

"To say we are delighted is an understatement," said Shaw. "It was ten years ago—in 1992—when JVHL was formed specifically to protect the outreach business of our member health systems through managed care contracting and other collaborative activities. By winning these major HMO contracts, we've validated that

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business strategy and, more importantly, we've helped our participating hospital laboratories protect and build their outreach testing programs."

The HAP contract illustrates why JVHL has become a potent competitor in Southeast Michigan. For at least seven years, **Quest Diagnostics Incorporated** held the exclusive laboratory testing contract for HAP, an insurance plan owned by the **Henry Ford Health System**.

A Successful HMO

"HAP has been one of the more successful HMOs in our region," explained Shaw. "Although much of this HMO's lab testing stayed captive within the health system, there was always a patient population served by outside providers and this was the lab testing contract held by Quest Diagnostics.

"Recently HAP acquired **SelectCare HMO**, a struggling HMO with about 70,000 lives," he said. "Because JVHL was the exclusive lab services provider for SelectCare, HAP began to meet with us over a variety of transition issues.

"HAP's own lab testing contract was up for renewal, so the timing of the SelectCare acquisition helped us," Shaw recalled. "The RFP process was intense, because both Quest Diagnostics and we wanted this contract."

Physicians Liked JVHL

Shaw believes HAP selected JVHL for two main reasons. "First, SelectCare physicians served by JVHL's member laboratories were quite satisfied with their laboratory services," noted Shaw. "They were not excited about the prospect of being forced to change to a national laboratory.

"A number of these physicians contacted HAP and expressed their wish to retain their existing laboratory," he continued. "This played a role, along with the fact that some ongoing service issues with HAP's current contract laboratory provider created an 'unmet need' which JVHL could fill.

"Second, JVHL can immediately provide HAP with lab data for HEDIS reporting which is more comprehensive than comparable data provided by either of the two national laboratories. This appealed to HAP," noted Shaw.

There is another notable fact about the HAP contract won by JVHL. Price was not the sole determining factor. "I am proud to say that the HAP contract was not awarded exclusively on the basis of price," declared Shaw. "JVHL is moving these contract award decisions based on the value of lab data that is useful to payers.

"Payers in Michigan have recognized this fact," he continued. "In recent years, as we acquired new managed care contracts, the HEDIS scores of these HMOs climbed in the years following their conversion to our laboratory organization.

HEDIS Scores Improved

"Payers are telling us that the lab data sets we provide are more complete and include a higher percentage of the results provided for the covered population of lives than any other lab provider, including the two national labs," added Shaw. "This was most clearly demonstrated by the HEDIS performance of the **Blue Care Network**, Michigan's largest HMO, once we became the exclusive lab testing provider."

The reason JVHL can provide more complete laboratory test data to the managed care plans is because the laboratories of its member hospitals do testing for the outpatient clinics owned and operated by these hospitals and health systems. "Commercial laboratories have never had access to these clinics and physician group practices," observed Shaw. "Because JVHL's hospital laboratory outreach programs serve these clinics, as well as physicians' offices not owned by a hospital or health system, JVHL has a more

Ten-Year Business Campaign To Win Managed Care Contracts Pays Off For Detroit Lab Network

OBTAINING MANAGED CARE CONTRACTS was the number one business goal of Joint Venture Hospital Laboratories (JVHL) when it became the nation's first operational regional laboratory network in 1992. In the past ten years, JVHL has successfully earned laboratory provider status with every major exclusive managed care contract in the Greater Detroit Metropolitan area.

MANAGED CARE CONTRACTS HELD BY JVHL

HEALTH PLAN	YEAR WON	#COVERED LIVES	# HOSPITAL LABS
DMC Care (*PPO*)	5/1/1997	5,000	74
Aetna U.S. HealthCare	12/1/1997	200,000	7
M-Care HMO *(POS, Grad Care, Medicare)*	9/1/1998	74,848	74
OmniCare Health Plan *(HMO)*, OmniCare Plus	7/1/1999	100,000	74
Midwest Health Plan *(HMO)*	9/1/1999	32,000	74
Cape Health Plan *(HMO)*	10/1/1999	44,000	74
The Wellness Plan *(HMO)*	12/1/1999	72,000	79
Beaumont Employee Health Plan (*PPO*)	1/1/2000	25,000	74
Care Choices *(HMO)*	1/1/2000	39,000	81
Care Choices (*PPO*)	2/1/2000	4,000	74
Blue Care Network *(HMO)*	4/16/2000	570,000	130
HAP Preferred Health Plan (*PPO*)	6/1/2001	21,000	74
Ulticare	3/1/2002	20,000	74
Ultimed	4/1/2002	17,000	74
HAP *(HMO)*	5/1/2002	125,000	74
	Total Lives:	***1,348,848***	

comprehensive set of laboratory data that it reports to the payers.

Customized Data Packages

"Payers tell us that these more complete data sets have value for them," added Shaw. "Moreover, during contract negotiations, JVHL tells managed care companies that 'we'll format lab data exactly as you want it.' Payers like this and tell us that our laboratory competitors only offer a limited number of lab data reporting formats."

It is a powerful endorsement for any laboratory when managed care plans will attribute improved HEDIS scores to the more complete lab test data sets they get from that laboratory provider. THE DARK REPORT points out that this accomplishment of JVHL is even more remarkable because it must collect lab test data from hospital laboratories throughout Michigan before it can send reports to payers.

Monthly, lab test data from up to 130 hospital laboratories data must be formatted and put into a common data repository before it can be transmitted to the health insurer in a form that is usable. Within the United States, this capability may be unique to JVHL. THE DARK REPORT is unaware of a comparable situation where lab test data from individual hospitals and integrated delivery networks (IDN) is

regularly gathered and submitted in a common format to a major insurer.

This achievement was a key part of JVHL's competitive business strategy. "Early on, JVHL recognized that HEDIS reporting requirements were an opportunity for us to add value to payers," noted Shaw. "During contract negotiations, payers had begun to ask us whether we could provide lab data formatted in specific ways.

Payers Had Unmet Need

"As payers told us how they would use lab data if they could get it in these formats, we recognized that it was an unmet need," he continued. "JVHL's board of directors made a strategic business decision to invest the time and money necessary to make this happen. It also required considerable commitment by our hospital laboratory members, since they must feed us their lab data in a common format.

"The challenges of combining lab test data from all our member labs should not be underestimated," commented Shaw. "It took several years of effort to develop and refine this capability. But the rewards justify the effort. JVHL is now a contract lab provider for every major HMO in Greater Detroit."

Most Effective Lab Network

THE DARK REPORT believes it is no accident that Joint Venture Hospital Laboratories is the single most effective regional laboratory network in the United States. First, it was organized for a specific business objective: to protect existing outreach business by its member laboratories and to support continued growth of outreach testing volumes.

This stands in contrast to the many regional laboratory networks launched in the second half of the 1990s which lacked a clear business focus and the urgency to accomplish a measurable financial objective.

Second, JVHL was organized to be economically self-sustaining. This also sets it apart from many other lab networks which require monthly payments from participating hospitals to cover expenses. JVHL was structured to generate sufficient revenue to covers its operational expenses. In fact, according to Shaw, JVHL has never tapped the initial capital funded by the original four health system owners.

Third, early in its operational life, JVHL had an executive director who was empowered to make decisions and devote time to the network's business needs. Having an executive with the time and authority to further the business interests of JVHL allowed the network to convert ideas into action and enabled it to achieve measurable financial goals.

Managed Care Contracts

Fourth, JVHL pursued managed care contracts with determination. It was professional and thorough in responding to RFPs and proved willing to invest in developing the types of lab testing services that had value to physicians, payers, and patients.

Fifth, JVHL declared that it would not compete solely on price. It wanted to differentiate itself by its ability to deliver recognizably better lab testing services daily to its client physicians. By not competing on price, JVHL was able to build a different type of business relationship with HMOs in the region.

The most important lesson that Joint Venture Hospital Laboratories teaches is that regional laboratory networks can be successful. But to achieve that, participating hospital laboratory members must move past issues of control and traditional cross-town rivalries and work with common purpose toward measurable financial goals and objectives. **TDR**

Contact Jack Shaw at 313-271-3692.

Cytyc Acquires Digene To Expand Product Line

HPV testing may become differentiator for liquid preparation Pap testing kits

CEO SUMMARY: Cytyc Corporation will pay more than one half billion dollars to purchase Digene, Inc., and its DNA Capture HPV test. For Cytyc, this may prove to be a strategic masterstroke. In the short term, it alters the competitive balance in the market for liquid preparation Pap testing products, where Cytyc already holds more than half of the market share for Pap testing in the United States.

COMPETITION IN PRODUCTS to screen for cervical cancer remains intense. The latest salvo in the Pap testing war is **Cytyc Corporation's** acquisition of **Digene Corporation**.

On February 19, Cytyc announced a definitive agreement to acquire Digene for a combination of cash and Cytyc stock. Market value of the transaction at the time of the announcement was $553.7 million.

The merger will put two products which have a close relationship under the same owner. Cytyc's ThinPrep® Pap Test and Digene's Hybrid Capture II® HPV test can both be performed from the same liquid specimen.

Growing Use Of HPV Test

In fact, Digene's efforts to expand HPV testing have been helped by the growing adoption of liquid preparation Pap smear testing in recent years. There is growing clinical use of HPV assays as an appropriate follow-up test for specific Pap smear diagnoses.

Cytyc gets one immediate competitive benefit from its acquisition of Digene. It will deny rival **TriPath Imaging, Inc.** the ability to piggy-back Digene's HPV test on the TriPath liquid preparation Pap smear test, called PREP-STAIN™ (formerly called PREP).

Cytyc To Block TriPath

TriPath has wanted Digene to perform the clinical studies that would support FDA approval for Digene's Hybrid Capture II HPV to be performed from the same liquid preparation specimen collected for TriPath's PREPSTAIN Pap test. However, once Cytyc takes ownership of Digene, that is unlikely to happen.

Cytyc and Digene already have a close relationship. A co-marketing agreement has existed between the two companies in recent years. Both companies have a mutual interest in building a portfolio of products involving screening for women's cancers and infectious diseases. As the acquirer, Cytyc gains access to the Hybrid Capture technology, patents, and the intellectual property developed by Digene.

Digene has been developing RNA and DNA probes. Its product portfolio includes gene-based tests for the detection of chlamydia, gonorrhea, hepatitis B virus, or HBV, and cytomegalovirus, or CMV. It also has FDA-approved tests for the simultaneous detection of chlamydia and gonorrhea infections, in addition to HPV, from a single patient sample.

Potential For Multiplexing

One simple way to view this merger is that it marries the specimen collection methodology developed by Cytyc with Digene's probe-based assays. The potential exists to combine these two product lines and create a series of multiplex tests for STDs, women's cancers, and similar applications.

However, the dynamics of this acquisition are more complex. As THE DARK REPORT has noted in earlier intelligence briefings, the market for enhanced Pap smear testing technologies remains highly competitive. Efforts by these companies to introduce their products reveal changes in how clinicians adopt them for general usage. It also provides insights into the new types of analysis now used by payers to determine the economic and clinical benefits of these new diagnostic assays before establishing billing guidelines and reimbursement levels.

Need For More Products

Cytyc understands that it must develop complementary products to supplant its liquid preparation Pap test. Otherwise, Wall Street considers the company a "one-trick" pony. Also, now that TriPath Imaging has FDA approval to market its integrated automated system for liquid prep and primary screening of Pap smear, it has begun to make inroads into a business line where Cytyc had formerly been the only choice for laboratories interested in offering liquid preparation Pap tests. *(See TDR, December 17, 2001 and January 28, 2002.)*

Laboratory executives and pathologists should keep a watchful eye on the market for Pap testing and HPV testing. The technology curve is moving rapidly. There are other players now offering HPV tests, such as **Ventana Medical Systems'** INFORM® Human Papilloma virus (HPV) ASR High Risk and Low Risk Probes and **Molecular Diagnostic, Inc.'s** In-Cell™ HPV Probe. More diagnostic companies are expected to enter this market.

Lots of research is also directed at finding molecular markers for cervical cancer. When that happens, the Pap smear loses its pre-eminence as the gold standard in cervical cancer screening. Companies like Cytyc and TriPath Imaging understand this, which is why they want to diversify and avoid a reliance on products that support Pap testing. TDR

Digene Working To Promote HPV Use As Primary Screen

SHOULD HPV BE USED in primary screening for cervical cancer? Digene Corporation thinks it should. It recently filed an application with the **Food and Drug Administration** (FDA) to permit its Hybrid Capture II HPV DNA test to be used "in conjunction with the Pap smear as a primary screen for cervical cancer and its precursors in women age 30 and over."

THE DARK REPORT predicts that Cytyc, once it owns Digene, will aggressively market HPV for screening. This campaign will be similar to the one it used to introduce ThinPrep as the "test of choice" in Pap smear screening. To raise awareness of female consumers, this campaign will include advertisements and news stories in women's magazines like *Cosmopolitan*, *Redbook*, and *Ladies Home Journal*. At the same time, it will press payers to authorize reimbursement for this test.

Lab Industry Update

Lab Test Manual Now Available on Handheld PDA Devices

HERE'S ANOTHER EXAMPLE of how technology is changing traditional laboratory practices. **Lexi-Comp, Inc.'s** *Laboratory Test Handbook* with information on 1,200 tests is now available as a software program for downloading onto the Palm Pilot handheld PDA (personal digital assistant).

Effectively, a handheld computer device can now replace the ubiquitous tome found on the shelves of lab test stations throughout the country. What gives this product added value is the fact that Lexi-Comp updates the software weekly, so the PDA can always have up-to-date diagnostic test information. In contrast, a book of lab tests becomes increasingly outdated as time passes and new technology hits the marketplace.

"To my knowledge, this is the first laboratory test manual that has been adapted for use with a PDA," stated Matt Kerscher, Nursing and Diagnostic Division Manager at Lexi-Comp. "We introduced the Palm OS version of this product in January and will have the Windows-powered pocket PC version ready in April."

Annual Subscription

This software product is sold on a subscription model. For an annual price of $75, the user can download updates for a full 12 months. The product contains the information from Lexi-Comp's *Diagnostic Procedure Handbook* and the *Laboratory Test Handbook*. There are 28 fields of information for each listing. Lexi-Comp has been publishing laboratory test handbooks since 1984.

Demand already exists to replace printed and bound manuals with a PDA loaded with the same information. Since its introduction of a pharmacy software product in August 2001, Lexi-Comp company has sold 10,000 units.

Information Age Impact

Although the arrival of a PDA-version of the *Laboratory Test Handbook* is a small event in the marketplace, it is a significant sign that the information age is steadily changing traditional business practices. For example, one national lab company has Lexi-Comp create a special version of the *Laboratory Test Handbook* for use by its own employees. Digital publishing makes this easier and less expensive, thus making it feasible for almost any laboratory to create a customized version of this database.

Packaging a laboratory test handbook into a PDA reflects the ongoing shift from paper-based data to digital data. Laboratory administrators and pathologists should consider opportunities within their own laboratory to digitize data that has traditionally been issued on paper and make it available to the internal lab staff as well as external users.

Being an early adopter of such services in local markets can provide laboratories and pathology group practices with a competitive edge. Of equal importance, digitizing data for electronic access and distribution is frequently cheaper than printing the same material on paper. . TDR

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Goal is to Reduce or Eliminate Payments to Paths

Pathology Part A Comp Under Attack by Both Hospitals and Insurers

CEO SUMMARY: In steadily-growing numbers, hospitals and insurers are taking active steps to reduce or eliminate compensation for clinical pathology professional services, also commonly referred to as "Part A" services. Unfortunately, many pathology groups fail to anticipate this situation until it's almost too late. In this DARK REPORT exclusive, attorney Richard S. Cooper identifies methods and strategies that local pathology group practices can use to mount an effective and successful response to the unjustified demands of hospitals, health systems, and insurers.

Second in a series

IT'S BEEN A TROUBLESOME TREND in the pathology profession for almost 15 years and efforts by hospitals and insurers to further reduce compensation for clinical pathology professional services have again intensified.

Bluntly said, growing numbers of hospitals and insurers are taking active steps to reduce, and even eliminate, compensation they pay for clinical pathology professional services (commonly called "Part A" services in reference to how Medicare defined hospital-based physician services under its DRG reimbursement scheme).

"The attack is double-sided," stated attorney Richard S. Cooper, a partner with **McDonald, Hopkins, Burke & Haber.** He has first-hand experience in Part A legal issues because his Cleveland-based law firm serves more than 100 pathology clients nationally.

"First, growing numbers of hospitals are not paying for Part A pathology services," he continued. "Second, in situations where pathologists are direct-billing for professional component clinical pathology services, growing numbers of payers are not only refusing to pay it, but more significantly, are instructing their insureds not to pay for it either.

"Of course, most pathologists are aware of several court cases in recent years where it was ruled that: 1) clinical pathology professional services were legitimate services, 2) pathologists were entitled to be paid for them, and 3) if the payer is not going to pay for them, the patient should pay for these services and the payer should not interfere with those payments by patients," explained Cooper.

"In the clinical laboratory, pathologists provide services at two levels," he noted. "First, they supervise the direct process of all testing. Second, they provide the medical expertise required to organize and deliver appropriate laboratory services. We've identified at least 21 distinct responsibilities provided by pathologists as part of their professional component services." *(See sidebar on page 14.)*

Effective Legal Strategies

Cooper pointed out that pathologists have several legal strategies to effectively counter the "no-pay" stance of growing numbers of hospitals and insurers. However, to use these legal strategies effectively, pathologists must take a proactive position on this issue.

In fact, THE DARK REPORT observes that the hospital and insurance industries' current challenge to clinical pathology professional services comes because the collective pathology profession has been generally reactive on this issue during the past decade. At the local level, many individual pathology group practices have not prepared for the day when their hospital or local insurer starts challenging the value of clinical pathology Part A services with the goal of reducing or eliminating compensation related to such services.

Attacks On Compensation

This is particularly true in negotiations between hospitals and their pathology groups. In situations where the pathology group has not educated the hospital administrators about the details and full scope of responsibilities involved in operating the clinical laboratory, it is increasingly common to see reimbursement for these services cut or eliminated.

On the other hand, Cooper says that, where hospital administrators understand the full range of activities and legal risks that are part of directing their clinical laboratory, they are much more likely to compensate the pathology group on an equitable basis.

Hospitals Seeking To Reduce Part A $s

THERE WAS A DAY WHEN VIRTUALLY EVERY hospital paid pathologists for clinical pathology professional services. However, that situation began to change during the 1990s.

"Prior to 1990, there was a very small number of hospitals that paid absolutely nothing to pathologists for Part A pathology services," observed Richard S. Cooper, Attorney and partner with **McDonald, Hopkins, Burke & Haber** of Cleveland, Ohio. "Today that number is increasing, although it remains small.

"The more significant trend involves hospitals which want to reduce Part A payments to pathologists," continued Cooper. "This results in a situation where pathologists receive inadequate amounts of compensation for the clinical pathology professional services they provide.

"Each year we see more hospitals take active steps to further reduce the amount of compensation paid to their pathology group practices for clinical pathology professional services," he said. "That is why it is important for every pathology group to anticipate this happening with their hospital or health system, and prepare, in advance, methods for defending the value of their services."

"To maintain fair compensation for these services, the best strategy is to educate the administrators," Cooper said. "This involves several steps. For example, it is important for hospital administrators to know and understand the opinions expressed by Medicare officials and the OIG on the issue of payment to hospital-based physicians for Part A services. Next, hospital administrators must also fully understand the depth and detail of the responsibilities executed by the pathology group as they provide medical direction for the clinical laboratory.

"I would suggest pathologists and their legal advisors look at the hospital model compliance plan," advised Cooper. "It states that the hospital could be in violation of fraud and abuse laws if it were to pay no reimbursement or token reimbursement for pathologists for Part A services in return for the opportunity to perform and bill for Part B services.

OIG Issued Advisory

"The Office of the Investigator General (OIG) issued an advisory on January 31, 1991 on this same point," continued Cooper. "The OIG cautions against arrangements with hospital-based physicians that compensate physicians at less than fair market value. This advisory specifically references no or token Part A compensation as a potential violation of Medicare fraud and abuse statutes.

"It is important to also remind administrators that the hospital is receiving compensation for Medicare Part A services," added Cooper. "When DRGs were implemented, it shifted the clinical pathology professional component from Part B to Part A. So the hospitals are receiving money for these services which should be passed to the pathologists."

Educating hospital administrators about compliance issues involving Part A compensation arrangements is only part of the strategy. These administrators must also understand the full spectrum of Part A services delivered to the hospital by its pathology group. That requires the pathology group to do several things.

"First, every pathology group should take a proactive position on Part A compensation," recommended Cooper. "This requires pathologists to prepare, in advance, for the negotiations they know will be inevitable.

"Next, they should identify and document all the tasks they perform within the hospital," he added. "This includes meetings, legal risks they assume when signing off on various lab activities, and activities that involve supporting the clinicians.

Successful Negotiations

"Keep in mind that the daily activities of a pathologist are different than other hospital-based physicians, such as radiologists," noted Cooper. "To be successful in these negotiations, your hospital administrator must understand what those responsibilities are and why they are different from those of other hospital-based physicians.

"As this step is completed, the next smart move is to survey what payment arrangements exist between other hospitals and pathology groups in the city and state," Cooper stated. "This information has great value in validating the pathologist's position and gives them confidence during negotiations that they are asking for reasonable compensation.

"In certain environments, I've seen another strategy work in favor of the pathologists," he observed. "In regions where managed care is important, pathologists should show the hospital how their professional services help to improve quality and control unnecessary costs. As healthcare becomes more data-driven, it places pathologists in an ever-stronger position to contribute more to the hospital's clinical effectiveness."

Build Relationships

One piece of powerful advice that Cooper offers centers upon the timeless value of the "schmooze factor." "Much of what happens in every hospital is based on relationships," noted Cooper. "It's been our experience that those pathology groups which had regular meetings and communications with hospital administrators, both professionally and socially, start from a much stronger position in these types of negotiations. These pathologists have made rapport and the human factor work in their favor."

Cooper characterizes these types of relationship-building activities as "preventive maintenance." He also recognizes that hospital administrators have their own responses to the points made by pathologists.

"The most common rebuttals are probably statements like 'We don't pay any other doctor for these activities, why should we pay you?' or 'The hospital has declining revenues and increasing costs and we expect the pathologists to share the impact of these trends," Cooper said. "Certainly these are not strong arguments and can be answered through the educational steps discussed earlier."

What If A Hospital Expands?

When negotiating Part A agreements, Cooper recommends that pathologists anticipate future expansion of the hospital or health system. "Whenever a hospital expands or adds new clinics and facilities, this creates additional work for the pathologists," explained Cooper. "For that reason, it is good to include some kind of mechanism in the contract so that the amount paid for clinical pathology professional services grows as the volume of work increases."

Insurance plans share the same motive as hospitals to trim back or eliminate reimbursement for clinical pathology professional services. "In our legal practice, we see a growing number of payers simply refusing to pay for these services," Cooper stated. "This includes payers who have historically made these payments, but then stop without any alteration of their contract language.

"I think that, under the language of the payers' own contracts, there is often a good argument that they are legally obligated to pay pathologists for these services," commented Cooper. "Effectively, this means the insurers are taking the position that these are services which should not be reimbursed.

"But since there is generally no financial adjustment in the premiums," he explained, "these insurers are putting their beneficiaries in the position where they will now get bills directly from the pathologists, but have received no premium offset from the insurer to reflect this change in benefits."

Interfering With Patients

These actions by payers are often accompanied by an active effort to dissuade patients from making payments directly to pathologists for clinical pathology professional services. "I know many pathologists have seen examples of an insurer telling patients not to pay these bills," said Cooper.

"This is unacceptable," he noted, "because there are federal and state court cases which have found these services to be legitimate and have ruled that pathologists have the right to be paid for them. Payers can certainly choose not to cover these services, but they cannot interfere with the physician's ability to bill and be paid for such services."

Cooper notes that pathologists have an effective solution to this problem. "These insurers are using the same tired arguments over and over," he declared. "For example, payers may say that Medicare and Medicaid does not pay for them, when in fact both do."

These payer arguments can be countered because they are factually inaccurate. "In our legal practice, it is not uncommon for a local pathology group to have more than one payer in their region begin to withhold reimbursement for these services," recalled Cooper. "We assist them in developing a 'self-help' response program with specific steps directed toward the payer and toward the individual patient.

Few Court Cases Filed

"Most of these situations are resolved without court action on the part of pathologists," added Cooper. "First of all, most patients, once they understand the issues, do want physicians to be paid for services that were rendered. So patients are generally cooperative in these matters.

"Second, federal case law on the subject of pathology professional services support the pathologist's position," explained Cooper. "Effectively used by pathologists, these arguments cause most payers to back down on this issue."

Cooper also noted that hospitals may prevent pathologists from billing payers and patients for these services if the hospital contract with the pathology group has a clause requiring it to agree to enter into managed care contracts. "This creates a problem if the payer doesn't want to pay for professional component services, yet the pathology group, because of its hospital contract, is obligated to accept that payer's contract. Obviously we advise our pathology group clients to refuse such clauses in their hospital contracts," said Cooper.

Attack On Compensation

In recent years, THE DARK REPORT has heard from a growing number of pathologists that compensation for clinical pathology services has come under intense attack in their city or region. It is a disturbing trend, because it financially undermines the important services required to produce high quality laboratory testing.

PATHOLOGISTS SHOULD DOCUMENT ALL RESPONSIBILITIES IN THE LABORATORY

There's one factor that's common to almost all successful negotiations between pathology groups and hospital administrators involving clinical pathology professional services. It is good documentation of all tasks and responsibilities handled by the pathology group practice in maintaining high quality laboratory services.

"The following list of 21 services is an excellent starting point for every pathology group that serves one or more hospitals," stated Richard S. Cooper, Attorney and partner with **McDonald, Hopkins, Burke & Haber** of Cleveland, Ohio. "Of course, in individual hospitals, some pathology groups perform services which go beyond this list. That is why it is important for pathology groups to conduct regular studies of the things on which they spend time."

1. The consideration of appropriate test methodology, instrumentation, reagents (agents used in laboratory testing, standards, and controls).

2. The establishment of test reference values and levels of precision, accuracy, specificity, and sensitivity.

3. The direction of laboratory technical personnel and advice to such personnel concerning testing.

4. Assurance that tests, examinations and procedures are properly performed, recorded, and reported.

5. Interactions with members of the hospital's medical staff regarding issues of laboratory operations, quality, and test availability.

6. The design of test protocols and the establishment of parameters for the performance of tests.

7. Recommendations regarding appropriate follow-up diagnostics tests when appropriate.

8. The direction, performance and evaluation of quality assurance and quality control procedures.

9. The evaluation of clinical laboratory data and the establishment of a process for review of test results prior to the issuance of patient reports.

10. The determination of the effects of medication on tests.

11. The determination of the effects of other analytes on test results.

12. The effects of other disease states on test results.

13. The establishment of turnaround times.

14. The criteria for urgent applications.

15. The prioritization of testing and testing sequences.

16. The application and response of values which require immediate medical consideration.

17. The determination of formats for reporting.

18. The establishment of referral criteria for review by pathologists and subsequent examination.

19. The determination of the type of data collection and storage criteria that will be used for particular tests.

20. The prevention of overuse and improper application of tests.

21. The assurance that the hospital laboratory complies with state licensure laws, certain accreditation standards, and certain federal certification standards.

In recent years, the growing number of "attacks" by hospitals, health systems, and payers on reimbursement for these services have popped up in different geographical areas at different times. This fact has made it difficult for the pathology profession to craft and implement a nationwide response strategy.

Until this occurs, the best defense of adequate reimbursement for clinical pathology professional services will come from the local pathology group practice. The tools of a successful defense have been presented here and local pathology groups should prepare themselves for these battles. **TDR**

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AACC's E-Lab Confab Emphasizes Lab Data

Experts demonstrate how new technologies will change the way labs deliver info to docs

CEO SUMMARY: In just six years, experts at the AACC's E-Lab gathering predict that 50% of all diagnostic testing will be done as point-of-care, homecare, or kit testing. If true, this will be a swift transformation in how labs organize themselves to manage the diagnostic testing needs of physicians, payers, and patients. Here are key insights from the meeting that affect both clinical labs and anatomic pathology groups.

By June G. Smart, Ph.D.

NEW INFORMATION MANAGEMENT technologies are about to enable speedy and far-ranging changes in how laboratories perform and manage diagnostic testing for healthcare.

This was a consistent theme at the AACC's "The E-Laboratory: A Critical Element in Laboratory Medicine Of The Future," held ten days ago in Miami. A carefully-selected faculty drilled in on how the full range of technologies—genomics, proteomics, Internet, software, hardware, and the like—will rapidly provide laboratories and anatomic pathology practices with incredible new capabilities.

Moving To A New Paradigm

This rapid change was probably best characterized when panelists agreed that, by 2008, as much as 50% of all diagnostic testing will be done in the form of point-of-care, homecare, and kits. For laboratories, this raises serious issues that include: 1) maintaining test quality and integrity; 2) capturing test results and getting them into the patient medical record; and 3), managing the dispersed testing process.

The predictions were potent and based upon how these new technologies are already shaping the lab testing market. For example, the impact of e-commerce can already be seen reshaping clinical transactions, according to Bruce Friedman, M.D., Director of Ancillary Information Systems, at the **University of Michigan Health System**. He expects clinical laboratories to be heavily engaged in e-commerce with the majority of transactions (OE/RR) Web-mediated.

Dr. Friedman's new lab information management highway integrates pagers, voice, PDAs, other gadgets with HTML browsers, voice services and secure on-line transactions. He pointed out that growing numbers of physicians can already access lab results and AP images in real time–with hands-free capability, allowing for "just-in-time" consultations. This

creates opportunities for lab professionals to become contemporaneous consultants to help clinicians deal with the anticipated increase in genomics-based assays and other esoteric testing.

One of the lab industry's shrewdest minds had two key observations. "Most laboratories use only half of their LIS's available features and functions," declared Sidney Goldblatt, M.D., Chairman and Program Director, Department of Pathology, **Conemaugh Memorial Hospital**, Johnstown, Pennsylvania. Dr. Goldblatt is the co-founder of **Sunquest** (recently acquired by **Misys**). "They already have the tools to do more with lab information, like data mining, that adds value to the lab's customers."

Dr. Goldblatt's second point involved strategic positioning for hospital laboratories. "Hospital labs have an advantage over **Quest Diagnostics** and **LabCorp**," he said from the podium. "Hospital labs have strong physician relationships, local access, inpatient and outpatient services, and complete patient records. These are assets that hospital labs should use to provide a better quality of lab testing services."

Learning About Options

As laboratory testing decentralizes outward from the core lab and into near-patient and point-of-care (POC) settings, laboratories that supervise this testing need to electronically link with the remote testing site. That underpins the recommendations of Gerald Wagner, Ph.D., Senior Vice President, Laboratory Testing Systems, **Bayer Corporation**, Tarrytown, New York.

"There are already devices in the marketplace which monitor populations in their home settings," said Dr. Wagner. "For example, **Matsushita's** Vital Signs Box remotely monitors blood pressure, glucose, temperature, and similar items. It is used in conjunction with an ASP (application service provider) for managing the data," he explained. "Results can be fed into a database, delta-checked, and sent wirelessly via the Web.

...panelists agreed that, by 2008, as much as 50% of all diagnostic testing will be done in the form of point-of-care, homecare, and kits. .

"In this type of situation, the laboratory can improve patient prognosis by linking other patient data or disease knowledge into results," noted Dr. Wagner. "This creates a higher service level, with data available 7/24. In doing this, the laboratory positions itself as a medical and diagnostic advisor even as the focus shifts from treatment to prevention. To succeed, laboratories must stake a claim to Web real estate and factor these issues into their strategic plan."

Echoing an emerging theme of specialized laboratory services was Jonathan Braun, M.D., Ph.D., Professor and Chair, Department of Pathology and Laboratory Medicine, **UCLA School of Medicine**, Los Angeles, California. He sees labs moving away from the generalist role, organized around core labs that provide almost any testing.

Labs Learn To Specialize

"I believe laboratories will increasingly specialize," he said. "They will spot opportunities and fill the emerging niches of risk assessment for various disease states, intervention planning, monitoring healthcare populations and providing clinical trials services."

Putting laboratory data to better use was the emphasis of Michael J. Becich, M.D., Ph.D., Director of the

Center for Pathology Informatics, at the **University of Pittsburgh Medical Center** (UPMC), Pittsburgh, Pennsylvania. "There are significant benefits for laboratories to marry pathology and oncology informatics with clinical trails data," explained Dr. Becich. "The Cancer Registry established a standards-based informatics system that now provides nationwide reporting consistency.

"However, silo mentality in fractured AP, CP and oncology departments often prevents such lab data from getting combined in useful ways," he added. Dr. Becich described an innovative project between UPMC and **Cerner Corporation** that is actively developing a link between a tissue bank containing enriched anatomic pathology data and the Cancer Registry.

"...the silo mentality in fractured AP, CP and oncology departments often prevents such lab data from getting combined in useful ways."

Of course, all the data flowing into laboratories can create "information overload" for management. This is particularly true of integrated and consolidated laboratories in multi-hospital health systems. In Milwaukee, Wisconsin, **ACL Laboratories**, the lab division of **Aurora Health Systems**, has attacked this problem.

"We've developed a sophisticated management reporting system," stated Jay Schamberg, M.D. General Manager at ACL Labs. "It's linked to 13 applications and data bases and can be accessed over the Internet. It gives us real time data on almost every aspect of the lab's activities."

In a live demonstration of the system, Dr. Schamburg could rapidly call up various key parameters of lab management, such as labor or supplies. From any starting point, this remarkable system allowed him to drill up or down to identify the specific management variable he was seeking.

Relevant Observations

After two provocative days of mixing futurist predictions with practical advice about changes already underway, the faculty sat as a panel. It offered two particularly relevant points. First, most existing LIS systems run on old software technology that is commonly eight or more years old. Thus most labs are not ready to meet the already-changing demands of the healthcare system.

Second, laboratories are focused on cost per test, not cost per disease. This is a mistake that lab managers must correct. Laboratories should begin integrating data from several sources for various disease states. The goal is to give physicians a complete picture to support improved outcomes. Panelists recommend that laboratories begin moving beyond simply producing and reporting data and offer physicians an analysis of the lab test data.

An E-Laboratory World

THE DARK REPORT concurs with E-Lab's experts. If their collective prediction is true and a sizeable volume of testing moves out of core labs during the next six years, then laboratories must reassess their strategic plans.

Those labs willing to partner with other industries, break down existing barriers, and be less risk-adverse will become a part of the E-health continuum and will be positioned to provide significant added-value to clinicians. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Down in Orlando, Florida, **Cognescenti Health Institute**, now opening a newly-constructed clinical laboratory, has selected **LabDat, Inc.** to provide browser-based lab test ordering and results reporting. In response to the anticipated changes caused by genomic and proteomic diagnostics, Cognescenti is building a laboratory business model that is organized around advanced informatics capabilities. *(See TDR, December 17, 2001.)*

SPECIALTY & BECKMAN

Multi-analyte test development is the goal of a recent agreement between **Specialty Laboratories, Inc.** and **Beckman Coulter Corporation** (BC). Specialty Labs will develop multi-analyte assays on BC's Progressive Micro-Array platforms. Beckman Coulter will have access to these assays as they are developed.

SIDE EFFECTS TO AIDS DRUG LINKED TO SPECIFIC GENES

Score one for pharmacogenomics. Two research teams, working independently, have determined that the AIDS drug, Zaigen, can cause potentially fatal side effects in individuals with specific genetic characteristics. Doctors at one research site, **Royal Perth Hospital** in Perth, Australia, are already screening AIDS patients for these genetic patterns before prescribing Ziagen or Trizivir (which also contains Ziagen). The other research team was from **GlaxoSmithKline**, manufacturer of these drugs. The preliminary studies indicate that, of the patients who experienced adverse reactions, between 50% and 70% had inherited a certain genetic variation.

ADD TO: Drug Reaction

The specific side effect is called "hypersensitivity reaction" and involves fever and a rash. It can be fatal if the patient continues taking the drug. Dr. Seth Harrington, Glaxo's Director of HIV and Clinical Development, stated that the cost of this genetic testing could be as little as $150 per patient. This early example of performing a diagnostic test panel prior to administering a prescription drug shows how quickly specific genetic-based discoveries move toward general clinical usage.

Quest, LabCorp Make "Best" AND "Worst" Lists

Here's a fun fact. On February 25, *The Wall Street Journal* published its list of Best and Worst Stock Performers. During the last three years, **Laboratory Corporation of America** placed third on the list, with annual compounded gains of 127.4%. **Quest Diagnostics Incorporated** placed ninth, at 100.4%. But as radio broadcaster Paul Harvey would say, "here's the rest of the story." On its list of the worst performers over ten years, LabCorp was ranked seventh worst, with a negative 5.3% compound return. **Corning Corporation**, which owned Quest prior to 1997, was 25th, with a negative .3% compound rate of return. It shows how devastating most of the 1990s was on the commercial laboratory industry.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 1, 2002.

PREVIEW #6

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