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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

Restricted information, see page 2

Commentary & Opinion by...

R Lewis Dark

Founder & Publisher

Profitable Prices for New Lab Information Services

ONE RESPONSE TO THE CONTINUED CUTBACKS for laboratory test reimbursement during the 1990s was a deluge of papers and speeches by pathologists and lab executives hammering at the theme that laboratory information possesses the potential to improve the quality of healthcare outcomes while reducing the cost of care. In the face of financially disastrous reductions in lab test reimbursement, laboratorians attempted to educate private payers and government health program administrators about the added value of laboratory testing.

Now it seems that the time has come for clinical laboratories and in vitro diagnostics companies to capitalize on the potential of laboratory test information to add value to the healthcare system. As you will read on pages 2-5, an increasing number of the largest MCOs (managed care companies) in Michigan are beginning to request additional laboratory information services. **Joint Venture Hospital Laboratories**, a regional laboratory network of 109 hospital laboratories statewide, is working to develop these enhanced lab information capabilities.

THE DARK REPORT believes the Michigan experience is typical of other major metropolitan markets. MCOs across the country are responding to the increased reporting requirements of HEDIS. But they are also beginning to look for tangible ways to improve healthcare outcomes while cutting the cost of care. Laboratory testing is one way to achieve both goals.

Thus, I predict that the age of "added value" laboratory information is almost upon us. This goes beyond the simple reporting of a single test result on a single patient to a single physician. It will involve laboratory medicine in more sophisticated data capture and data analysis. The resulting knowledge from this lab information will be worth a lot of money to payers, physicians, and patients.

For the laboratory industry and the pathology profession, this is a crossroads in the healthcare marketplace. Sophisticated management of lab information will create value, but labs will incure costs to produce this information. Can laboratories and pathologists successfully price these enhanced laboratory information products to capture some of that added value? To do so will require pricing discipline and more sophisticated management understanding of the competitive healthcare marketplace. Both were lacking in the early 1990s when capitated lab services contracts hit the marketplace. To avoid deja vu, this generation of lab executives and pathologists must apply proven management tools to the pricing and selling of the emerging, added value, lab information products. TDR

MCOs Asking For More Lab Test Information

Demand for information based on lab testing outruns ability of labs to provide such info

CEO SUMMARY: During the past 12 months, managed care companies in Michigan have increased the quantity and quality of the laboratory test information they want from their laboratory providers. Once again, the marketplace is raising the bar for competitive laboratory services. In response, Joint Venture Hospital Laboratories has made strategic lab information services its number one business priority.

THERE'S A NEW CLINICAL LAB industry trend now revealing itself in the marketplace for healthcare services.

"During the past 12 months, we've seen a definitive shift in how MCOs (managed care companies) select their laboratory providers," stated Jack Shaw, Executive Director of **Joint Venture Hospital Laboratories** (JVHL), headquartered in Detroit, Michigan.

"Formerly, insurers in Michigan were primarily interested in whether a laboratory provider had adequate patient access points in areas where the beneficiaries lived and worked, as well as quality testing resources and basic reporting capability, mostly on test utilization," noted Shaw. "That emphasis has changed.

"A growing number of MCOs in Michigan now want expanded laboratory information capabilities from their clinical lab providers," he continued. "Their demand for lab information reaches beyond basic test utilization and HEDIS-required lab data.

"At JVHL, we view the MCOs' interest in more sophisticated lab information products as a great business opportunity," explained Shaw. "But there is bad news and good news associated with this opportunity.

"The bad news is that not all member labs in our regional laboratory network have the capability to readily gather this laboratory information and present it to the MCOs. The good news is currently no competing laboratory in Michigan can do it either," observed Shaw.

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"If I were to characterize the changes we see in how managed care companies contract for lab testing services in Michigan, it would be simple: 'information management of lab test data is now king'," said Shaw. "Some of the biggest insurers in Michigan made it clear to us that our regional laboratory network must be able to deliver more sophisticated lab information if we are to continue as their provider.

"More importantly, this is not a one-time change. These MCOs are telling us that we must continuously upgrade and expand the types of lab information we provide them," continued Shaw. "From a strategic business perspective, JVHL now considers lab information to be its top priority. This is a change from one year ago.

Information Highway

"In our markets, MCOs are flying down the information highway," he said. "Only recently, it was adequate for lab providers to simply report utilization data and basic HEDIS-specified laboratory test restults.

"Now we see individual MCOs in Michigan requesting that the laboratory deliver all the test results, not just those tests involved in HEDIS reporting. One MCO even wants these test results reported in LOINC format [Logical Observation Identifier Names and Codes]," Shaw stated.

"For JVHL, this is a wonderful business opportunity. If we can be first in our market to deliver enhanced laboratory information services to local MCOs, then we will have a competitive advantage over the commercial labs competing for the physicians' office business," he said.

"Moreover, JVHL, as a network of hospital laboratories, has something which the MCOs clearly want, and which commercial labs cannot provide. That is the test data for hospital outpatient testing [compared to hospital inpatient and physicians' office outreach]. JVHL's 109 hospital laboratories have that outpatient test data.

Lack Of LIS Products

"What holds us back is the lack of LIS products capable of doing the job," added Shaw. "Every hospital lab administrator is familiar with the problem. For example, existing LIS clinical data repositories cannot link the patient's test results with his health insurance. Concerns about HIPPA policies and the privacy of patient data also need resolution.

"We are searching diligently for a lab information services vendor which can help us efficiently aggregate the test data from our member laboratories and package it to meet the needs of our MCO customers," he continued. "We are frustrated by the vast amount of vaporware and vendor hype that we encounter.

"So far, not one lab-based IS vendor we've talked with has a product ready for market," he observed. "Ask these vendors to let us visit a laboratory site where their IS solution is already operating and they become masters of the dance. It is very difficult to get straight answers to simple questions about what their products do, and when these products will actually be ready for the market."

Frustration With IS Vendors

JVHL's frustration with IS vendors may lead it to design its own information product. "We already have an internally-developed program for electronic reporting of test utilization data from our member laboratories," he explained. "Several years back, it was faster and cheaper for us to develop our own electronic reporting solution.

"Meetings and interviews with LIS vendors to date make us think we

Five Strategic Drivers Now Guide JVHL's Strategic Business Plan

SINCE ITS INCEPTION IN 1992, Joint Venture Hospital Laboratories (JVHL) has operated with clearly-defined strategic business goals.

It was designed to be financially self sufficient, something that many other pioneering regional laboratory networks failed to do. Consequently, JVHL has met the expectations of its laboratory members, while generating the cash flow it needs to be a viable laboratory service organization. That is one reason why it has grown to include 109 hospital laboratory members and encompasses the entire state of Michigan.

Executive Director Jack Shaw outlined the current strategic priorities for JVHL. "There are a couple of things we try to accomplish with our strategic priorities," he observed. "One, we want to have a vision of what JVHL will be as we accomplish these goals. Two, we want to develop multiple management projects. Our healthcare marketplace is evolving too rapidly to allow us the leisure of concentrating on one management priority at a time." Here are JVHL's strategic goals:

1 Be the preeminent outpatient and community based laboratory services provider organization to patients, physicians and payers in Michigan. Explore multi-state contracting opportunities with compatible organizations.

2 Implement an expandable electronic functionality that will efficiently gather and consolidate the test results data reported to JVHL by its network laboratories in format(s) accepted by MCO clients. Functionality must include future use of LOINC coding and "all results" reporting.

3 Eliminate the use of UB92 or HCFA 1500 claims by all JVHL network laboratories for JVHL lab agreements, by offering sufficient electronic billing services options — direct reporting or commercial vendors (i.e., NDC, HDS).

4 Obtain a license as a Michigan third party administrator (TPA) to meet new Michigan managed care risk-sharing regulations. Investigate best uses of TPA functionality to support associated priorities.

5 Expand group purchasing and shared services initiatives to reduce network laboratories' costs.

may be better off developing our next generation of lab information services internally," added Shaw. "This is not the daunting task it would have been five years ago. The Internet and new software technology is making it easier, faster, and cheaper to engineer our own lab information solutions."

Successful Lab Network

Joint Venture Hospital Laboratories is probably the nation's most successful regional laboratory network. It was founded in 1992 by four integrated hospital systems in the Detroit metropolitan area to protect existing outreach testing business. Member labs have joined at a steady rate. Currently JVHL has 109 participating hospital laboratory members throughout the state of Michigan.

JVHL has been extremely successful at managed care contracting. It now covers 1.6 million lives, including **Blue Care Network**, Michigan's largest private HMO. As a result, JVHL has a strong market presence in the state and competes effectively with the national laboratory companies.

"Over the last year, we were quite surprised at how quickly certain MCOs became interested in getting expanded laboratory information services and started to write new information requirements into the RFPs for lab services," recalled Shaw.

Managed care companies are waking up to the fact that clinical laboratory test data has tremendous value in improving the quality of care while simultaneously reducing the cost of care.

"Preparing to meet this change in the lab information needs of the managed care companies is now the major subject we talk about at every management meeting," he stated. "It's the strategic business objective that's become the priority over everything else.

"As a regional lab network, we consider laboratory testing to be a local business. JVHL's role is to help individual hospital laboratory members get themselves in front of their local physicians. The individual hospital labs keep their names in the doctor's mind, while JVHL offers back stop services," concluded Shaw.

Market Evolution

THE DARK REPORT believes that the changing lab information requirements wanted by managed care companies in Michigan is typical of many regional healthcare markets across the country. Managed care companies are waking up to the fact that clinical laboratory test data has tremendous value in improving the quality of care while simultaneously reducing the cost of care.

JVHL was alert to the evolving needs of its managed care customers. As the first MCOs began to request additional laboratory information services as part of their RFP packages, executive management at JVHL recognized that a fundamental change was occurring in how MCOs would contract for laboratory testing services in the future.

JHVL took immediate action to act upon this market insight. It decided to invest time and management resources to create these new, more sophisticated lab information services. To that end, JVHL has already interviewed a number of LIS vendors seeking the right IS solution. It is contemplating whether to develop new LIS capabilities as an in-house project or in partnership with an outside vendor.

These are both elements critical to JVHL's sustained financial success as a regional laboratory network. Essentially, the JVHL executive team is alert to shifts in the competitive makeup of its healthcare marketplace. It is then willing to act swiftly and invest in upgrading its services to meet these competitive challenges.

Marketplace Evidence

For laboratory executives and pathologists, the Michigan marketplace provides evidence that the hunger of MCOs for more comprehensive laboratory testing information is about to explode on the upside.

None of this should come as a surprise to clinical pathologists and laboratory executives. After all, the ability of diagnostic testing to deliver improved healthcare outcomes at declining costs has been a constant theme of lab industry papers and podium presentations throughout the 1990s.

Now the MCOs are finally listening. The question is a simple one: will pathologists and lab executives be willing to respond swiftly to the very opportunity they have vociferously advocated for ten years? TDR

Contact Jack Shaw at 313-271-3692.

Medicare HMO Program Debates Funding Levels

Rapid growth of Medicare Choice program threatened by claim of HMO overpayments

CEO SUMMARY: Medicare+Choice was to offer seniors insurance options that went beyond standard Medicare fee-for-service services. Through the 1990s, seniors enrolled in Medicare HMOs at phenomenal rates. A recent GAO report repeated claims that Medicare HMOs are overfunded, to the tune of $5.2 billion per year. Congress must now consider a dozen bills seeking increased reimbursement for Medicare HMOs.

RAPID ENROLLMENT GROWTH in commercial HMOs during the 1990s was matched by equally rapid enrollment growth in Medicare Choice+HMOs.

Medicare HMOs attracted seniors by offering, at modest additional charge, prescription drug benefits and other benefits not available in traditional Medicare. These features fueled rapid enrollment growth in such plans. In that regard, Medicare HMOs were a consumer success.

For clinical laboratories and pathology group practices, the growing proportion of seniors shifting from Medicare fee-for-service to Medicare HMOs meant reduced access to these patients as well as a definite decline in net reimbursement.

Potentially Significant Trend

THE DARK REPORT labeled this shift into Medicare HMOs as a potentially significant trend if it continued into future years. This trend would be particularly relevant for anatomic pathologists. *(See TDR, December 29, 1997.)*

Seniors are relatively high-volume users of AP services. If increasing numbers of seniors entered Medicare HMOs, exclusive, full-risk, capitated contracts would restrict pathologist access to these patients. Medicare HMOs would also pay those designated pathologist providers much less money per episode of care than Medicare's fee-for-service reimbursement.

During the last three years, private insurers have terminated their Medicare HMOs in a number of markets, claiming insufficient reimbursement to sustain operations. A total of 1.6 million seniors enrolled in these plans were forced to switch to a different plan as a result of these closings.

On the government's side, the perception is that Medicare HMOs are overpaid. The problem that dogs private Medicare HMOs is the charge that these plans recruit only the healthy population, leaving Medicare fee-for-service to treat the chronically ill. The problem is called "favorable selection" and HCFA has struggled for years to deal with this issue.

A just-issued report by the **United States General Accounting Office** (GAO) is generating increased debate about favorable selection and the Medicare+Choice program. The GAO concluded that, for fiscal 1998, Medicare spent $5.2 billion more for care of enrollees in Medicare+Choice plans than if these same enrollees had been in the traditional Medicare fee-for-service program.

Healthy Seniors

"There has always been the contention that Medicare HMOs get a disproportionate enrollment of healthy seniors, so it's claimed that the premiums they get from Medicare represent overpayments," said Susan Pisano, Vice President of Communications at the **American Association of Health Plans** in Washington, DC.

"Yet, the government has never measured the actual health services used by seniors in private Medicare HMOs," she observed. "Generally, it measures the health of the enrollee in the year prior to enrollment. Such studies do not accurately gauge health services provided to that enrollee by the Medicare HMO in subsequent years.

"The reimbursement squeeze noted by the Medicare HMOs is triggered by the fact that year-to-year increases in Medicare premiums have gone up by 2%, while the expenses of these plans have increased 10% annually in recent years," explained Pisano.

Congressional Action

Congress may be forced to act upon this issue during the fall session. According to Pisano, the Medicare HMOs are requesting funding increases of $15 billion over the next five years. Countering this request is the argument by HCFA and the GAO that "while health plans tended to enroll less-expensive beneficiaries, Medicare's payments were too generous because they were based on the expected costs of enrollees in average health." *(GAO/HEHS-00-161, page 8.)* As a point of reference, HCFA reports that 10% of all Medicare beneficiaries account for 63% of all Medicare expenditures.

In the GAO report, government administrators advance the argument that "...many of the additional benefits enjoyed by plan enrollees may have been the result of Medicare's overly generous payment rates, not of efficiencies achieved under managed care."

Although the objective of the Medicare HMO program was to expand choice and consumer options, government administrators now use these plan features as an argument to reduce Medicare HMO premiums.

Debate Is Changing

"Fortunately, this debate is changing," noted Pisano. "An increasing number of Congressional members from both sides of the political spectrum are recognizing the benefits of consumer choice that Medicare HMOs provide to seniors. There are a dozen bills pending which would increase reimbursement.

"As Congress deals with this issue in the next 6 weeks, the basic question is whether or not Medicare HMOs will get the funding they need to flourish in coming years," concluded Pisano.

For laboratory executives and pathologists, this issue will have a direct financial impact. Any decisions that lead to further gains in Medicare HMO enrollment will have long-term financial impact in laboratories.

Further, THE DARK REPORT believes that the political debate involving Medicare HMOs will become part of the ongoing battle between those who want a government-run national healthcare system and those who favor a private healthcare system that is built upon consumer choice. TDR

Contact Susan Pisano at 202-778-3245.

Lab Industry Trends

Quest Diagnostics Emphasizes Venture Capital Investments

ONE SIGNIFICANT business strategy in play at **Quest Diagnostics Incorporated** is venture capital investing.

With $3 billion in sales, Quest Diagnostics is the largest clinical laboratory company in the United States. It understands that the traditional lab sales strategy of marketing to physicians' offices can no longer support the company's needs for sustained, rapid growth.

Equity Opportunities

That is one reason why Quest Diagnostics is willing to develop equity investment relationships. To help further this business strategy, it organized a wholly-owned subsidiary, called **Quest Diagnostics Ventures, LLC**. The company wants to develop equity investment opportunities that tie into diagnostic medicine.

Recently Quest Diagnostics announced a $7.1 million investment in **GMP Companies, Inc.**, based in Fort Lauderdale, Florida. GMP is a private company that "acquires, develops, and commercializes promising pharmaceutical, diagnostic, device, and biotechnology products." It does this through licensing agreements with academic medical research institutions.

Also, last month Quest Diagnostics Ventures, LLC completed an investment transaction with **MedPlus, Inc.** by paying $8.0 million for 1.92 million common shares of MedPlus. Combined with an earlier investment of $2 million, Quest Diagnostics' holdings represent 18.4% of the voting stock of MedPlus. Quest Diagnostics also holds warrants for an additional 12% interest in MedPlus.

MedPlus sells an electronic patient records system. Last June, Quest Diagnostics inked an agreement with MedPlus. Both companies will jointly market MedPlus' ChartMaxx and the Internet-based E.Maxx Enterprise-wide Patient Record system.

In January, Quest Diagnostics signed an agreement with **Cytyc Corporation**, maker of the ThinPrep® liquid preparation Pap smear product. Quest Diagnostics will market ThinPrep on an exclusive basis. This marketing agreement granted Quest Diagnostics a warrant to purchase 150,000 shares of common stock in Cytyc.

New Business Partnerships

Quest Diagnostics' willingness to participate in equity investment opportunities demonstrates how different the "new economy" will be from what we know today. Collaborative business relationships will be more common. These types of arrangements are already easy to find among diagnostic manufacturers who sell their equipment and reagents to laboratories.

But shared marketing and equity arrangements are almost impossible to find among healthcare providers. Progressive lab owners and pathologists may want to reassess their traditional "go-it-alone" attitude and explore these types of business opportunities. TDR

CEO SUMMARY: Various new technologies intended to supplant conventional Pap smear screening must deliver improved clinical performance in a cost-effective manner. Joseph Plandowski, our guest writer, concludes his three-part series on new Pap smear technologies by evaluating actual lab costs of the specific Pap smear technologies. His conclusion is that reimbursement drives the adoption rate of these products.

WHAT ARE REAL-WORLD COSTS?

Accurate Costing of New Pap Technology Proves Interesting

LAST OF A SERIES

BY JOSEPH PLANDOWSKI

EDITOR'S NOTE: In this final installment of our series on new Pap smear technologies. Joseph Plandowski provides some basic examples of the lab cost versus reimbursement for various Pap smear products. He believes the adoption rate by clinical laboratories will be directly tied to adequate reimbursement.

INTRODUCING NEW MEDICAL technology into the American healthcare system implies that each generation of enhanced Pap smear products must undergo a careful cost-benefit analysis.

Of equal importance is reimbursement. The most successful manufacturers of enhanced Pap smear technologies seem to spend as much effort on educating payers as they do introducing the products themselves to laboratories and physicians.

Individual laboratories face a complex decision when evaluating whether to incorporate specific new Pap smear technologies into the test mix. The economics of these new technologies are just as important as the clinical benefits they are expected to deliver.

In my experience, the introduction of new testing technology always generates greater costs than either what the vendor represented or what the lab estimated. That seems to be quite true when developing a cost picture of the new Pap smear technologies in actual, high volume, laboratory settings. There are often several cost items which are generally unmentioned by the vendor and often overlooked by the lab. For example, there is the additional cost of kits and labor used in retesting (at no charge) patients whose first Pap smear was labeled "unsatisfactory" or "not able to diagnose"

I would like begin by reviewing the liquid preparation Pap smear products. Two products have FDA clearance for use within the United States. One is **Cytyc Corporation's** ThinPrep®, the other is **TriPath Imaging, Inc.'s** PREP®.

It is important to understand that costs are substantially increased in a laboratory that adds the thin layer preparation (TLP) Pap test to its test menu. Assume a laboratory has an annual volume of 50,000 Pap tests and operates 250 days per year with $10.00 per hour laboratory aide labor. The conventional Pap test in this laboratory may cost $13. This includes $1.00 for the Pap smear collection kit provided to the physician's office; $2.00 for accessioning, staining, and coverslipping; and, $10.00 for cytotech screening, diagnosis, and quality control of the Pap Smear slide.

With TLP Pap testing comes the cost of the TLP kit, depreciation of the processor, and labor to operate the processor and/or prepare specimens for the processor. Price of the processor is about $50,000. List price for Cytyc's processor is $49,000. TriPath's processor lists at $55,000, and includes automated staining.

At a five-year useful life, depreciation is $10,000 per year, or $0.20 per slide. Lab aide labor to operate the processor and/or prepare the specimen for processing is $80 per day for 200 slides per day, or $0.40 per slide. Obviously, the annual volume of Pap smear tests done in a particular laboratory has a big impact on the resulting average cost per slide.

List price of Cytyc's ThinPrep is $10.75 per kit. Add to that amount depreciation at $0.20, labor at $0.40, accessioning, staining, and coverslipping at $2.00, and screening, diagnosis, and quality control at $10.00. This yields a cost of $23.35 per Cytyc ThinPrep Pap test. It is about 80% greater than the 13.00 cost of the conventional Pap test used in this example.

TriPath's PREP cost is similarly computed, except its TLP kit list price is $6.95 when the processor is purchased. When the processor is loaned, the list price per kit rises to $7.95. Its processor automatically stains the slides, but it does require additional lab aide work to centrifuge the

Basic Costing for Thin Layer Pap Smears

These tables were presented by Joseph Plandowski at the EXECUTIVE WAR COLLEGE in New Orleans, held May 16-17, 2000. They show basic cost calculations for the conventional Pap smear, ThinPrep Pap smear, and PREP Pap smear. The tables on page 13 show how weighted reimbursement determines the economic effectiveness of these new Pap smear technologies.

CONVENTIONAL PAP (CP)*

Assume the following:

- Cell Collection/Slide Prep is $3.00 (includes $1.00 PAP kit for MD office)
- Screening/Diagnosis/QC is $10.00 (includes 10% QC rescreening)

Summary: Current CP cost is $13.00

COSTS-THINPREP

These costs are additive to lab's current cost for manually screening Pap Smears:

- ThinPrep kit at $10.75; less $1.00 Pap kit
- Device depr. $0.20; labor $0.40; assuming:
  - 50,000 PAPs per year; 250 workdays per year
  - $49,000 device cost; 5 year use; labor $10/hr
  - Device processes 200 slides per day

Summary: Current CP Cost + $10.35

CONVENTIONAL PAP (CP) *VERSUS* TLP COST ESTIMATE

- CP $13.00 + $ 0.00 = $13.00
- ThinPrep $13.00 + $10.35 = $23.35
- PREP $13.00 + $ 6.57 = $19.57

COSTS: PREP

Analysis similar to Cytyc's ThinPrep

- PREP kit $6.95; less $1.00 Pap kit
- Device depr. $0.22; labor $0.40; assuming:
- 50,000 Paps per year; 250 workdays per year
- $55,000 device cost; 5 year use; labor $10/hr
- Device processes 200 + slides per day

Summary: Current CP Cost + $6.57

** College of American Pathology Analysis: Costs of Conventional Pap Smears (CP)*
Go to internet: "www.cap.org"; select: "Advocacy"; select: "CAP Government Resources";
From "CAP Prepared Documents," select "Pap Test Cost Model" and then print page.

specimens. Hence, the total cost of TriPath's PREP Pap test is $19.57. That cost is about 50% greater than the cost of the conventional Pap test used in this example.

One important operating issue that a laboratory must consider is how many of its current clients will order the TLP Pap test. If a laboratory does 50,000 Pap tests per year but only 30% of those are specified as TLP Pap smear tests, the cost of those fewer TLP Pap tests increases. This is not a hypothetical issue. Transition costs must be considered because they will occur and they may be substantial.

In conventional Pap smear testing, for example, the laboratory provides Pap collection kits to its clients that cost $1.00 or less each. With the TLP Pap test, each kit is substantially more expensive. The laboratory will need to make a significant capital investment to place a sufficient inventory (with a limited shelf life) of TLP collection kits into all the offices of its physician clients.

Further, during transition to full conversion, two types of kits must be handled and inventoried. And, only trained cytotechnologists can read TLP Pap tests. If the TLP test volume is low, it is difficult to maintain cytotech proficiency at acceptable levels. Slides must also

be carefully sorted so only TLP-trained cytotechnologists get TLP Pap tests for screening. The transition process from conventional Pap smears to TLP Paps requires careful management because it is unlikely that full conversion will occur in many laboratories in the foreseeable future.

Area Of Concern To Labs

Reimbursement of the TLP Pap test has received much attention but is still an area that should be of concern to laboratories. Congress recently enacted a very significant increase in Medicare's reimbursement for the conventional Pap test, raising it from $7.15 to $14.60.

At an assumed cost of $13.00 for the conventional Pap test, Medicare needs to reimburse Cytyc's ThinPrep Pap test at $23.35 for breakeven to occur. The $10.35 differential is the added cost of performing a ThinPrep TLP Pap test from the example presented. TriPath's PREP would need a reimbursement of $19.57 for breakeven to occur.

Current Medicare reimbursement for the TLP Pap test is regionally determined by "gap-filling." It was $21.00 in California, $21.45 in New York, $14.50 in Texas, $17.00 in Florida, $16.50 in Illinois, $12.00 in Minnesota, and $7.15 in Virginia. Recently these fees have increased to as much as $28.50. A national fee is expected to be established by Medicare later this year.

Looking at automated Pap smear screening, currently only one product has FDA clearance for use in the United States. It is TriPath's AutoPap® Primary Screening System.

"Fee Per Use" Contract

The cost for screening Pap tests on the AutoPap System must be calculated on a weighted basis. TriPath provides systems in the USA on a "fee per use (FPU)" basis with agreements generally four years in length.

The FPU rate may be as low as $3 per slide in the first year. However, over the four-year term TriPath averages at least $5 per slide. For example, if the client begins at $3 per slide in year one, they may move to $5 in year two and then $6 to $7 per slide in years three and four.

FDA requires 75% of the slides put through AutoPap, as a primary screener, be manually screened. The remaining 25% of the slides, diagnosed as WNL, will be assumed to cost an average of $5 each. Also assume for this exercise that the remaining 75% of the slides are screened by a cytotechnologist at a cost of $10 each.

On the surface it appears that AutoPap is a bargain. However, the economics are somewhat more complicated. Assume 100 "risk-free" slides are put through the AutoPap System. That costs $500 (100% x 100 x $5). The 75% portion screened by a cytotechnologist costs $750 (75% x 100 x $10). The total is $1,250 to process 100 slides. To screen all 100 slides manually costs $1,000 (100% x 100 x $10).

Rescreening Rates

That represents a 25% cost premium for using the AutoPap System. And, that's without considering "high risk" slides in the 100 slides that must be screened manually, or without considering the 15% rescreen rate when using the AutoPap System versus a 10% rescreening rate for manual screening.

TriPath Imaging is currently working for FDA approval of a combined PREP and AutoPap system. This would marry the PREP automated liquid preparation instrument to the automated AutoPap Primary Screen system. Company officials believe that, as a combined instrument suite, they can offer laboratories a total list price of under $8.00 per Pap smear test.

Basic Costing for AutoPap Procedure

At right is the table showing basic cost data for the AutoPap procedure. The table at bottom left shows how to calculate a weighted average reimbursement. In the table at bottom right, this reimbursement is compared to the costs of the conventional Pap smear and the thin layer preparation products.

COSTS: AUTOPAP

- 100 "no-risk" slides; $5.00 per slide rental
- 25% to file; 75% to manual screening
- 15% FDA-mandated QC versus 10%
- $10.00 CP screen/diagnose/QC cost
- [100x$5 + (75+5)x$10] / [100x$10] = 1.30
  1/2 FTE labor; $10/hr; 200 slides/day

Summary: CP Cell Collection/Slide Preparation + 1.30 x CP Screen/ Diagnose/QC Costs + Labor Costs

Summary: $3.00 + $13.00 + $0.20 = $16.20

REIMBURSEMENT EXAMPLE

Payers	Mix%	CP$	TLP$
Medicare	15	14.00	20.00
Medicaid	10	7.00	13.00
HMO	30	9.00	14.00
Client	25	6.00	18.00
Patient	20	30.00	40.00
Wgtd Avg		***$13.00***	***$21.00***

CP vs. TLP PROFITABILITY EXAMPLE

Method	Reimb$	Cost$	Margin$
Conv. PAP	13.00	13.00	0.00
ThinPrep	21.00	23.35	-2.35
PREP	21.00	19.57	1.43

And, don't forget transition costs!

Were this to prove true, it would definitely improve the economics of TriPath's automated systems over conventional Pap smear screening methods. The arrival in the marketplace of an FDA-cleared automated liquid preparation/automated primary screening system would also change the existing competitive balance between Cytyc and TriPath Imaging.

Cytyc has yet to weigh in with some type of automated Pap smear screening system that can tie into its ThinPrep TLP system. Cytyc will certainly be aggressive at protecting its early lead in the cervical cancer screening marketplace. But the specific way in which Cytyc might respond to TriPath's possible $8.00 automated liquid prep/automated screen product is unknown.

During the three installments in this series, I have tried to highlight two basic aspects of the various new Pap smear technologies. One aspect is the clinical performance of these products, as demonstrated in clinical studies and from the anecdotal experience of laboratories which were early adapters. This was covered in installments one and two. *(See TDR, June 19, 2000 and August 21, 2000.)*

Compelling Economics

The second aspect is the cost of these technologies as compared to the cost of conventional Pap smear methods. As this third installment demonstrates, the current generation of new Pap smear technologies does not offer *compelling economic advantage* over a conventional Pap smear.

This brings up an interesting question. If cost-benefit studies generate mixed results about the actual performance of certain of these various technologies against the conventional Pap smear; and if these products cost more than conventional Pap smears, then why has at least one of these products

captured a significant share of the Pap smear market?

I believe the primary answer lies in reimbursement. In regional markets where payers have given generous reimbursement for the CPT codes associated with liquid preparation Pap smears, clinical laboratories have an economic incentive to offer this technology to clinicians.

Generous Reimbursement

Thus, in these areas of the country, the liquid preparation Pap smear has a higher ratio of utilization compared to conventional Pap smears. In regions where payers have been less generous with the reimbursement connected to these CPT codes, liquid prep Pap smears are not used as frequently.

If, in fact, it is generous reimbursement for these CPT codes that actually drives laboratory acceptance of TLP technology, there may be an interesting consequence. Remember what HCFA and private payers did to slash reimbursement (and utilization) for high-volume chemistry panels in recent years?

If the TLP Pap smear is seen to have no clearcut and indisputable economic benefit over conventional Pap smears, Medicare and private payers might decide to cut reimbursement for the CPT codes associated with TLP Pap smears as a way of discouraging a technology they consider to have marginal clinical benefit against increased costs of 50% to 80% per test.

Another Wild Card

There is another wild card in this equation. That is **Digene, Inc.'s** Hybrid Capture HPV® (human papilloma virus). Clinical evidence is accumulating that some combination of Pap smear screening and HPV testing may be more effective than just conventional Pap smears alone. This may create a new equation of clinical benefit versus cost which works for or against liquid preparation technologies and automated Pap smear screening.

I can, however, make one prediction with confidence. Within the field of women's health, there will be ample and heated debate about the benefits and costs of these new cervical cancer screening technologies for some years to come. The final chapter is far from being written! TDR

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"Capacity Expansion" Pap Smear Model

LABORATORIES DOING HIGH VOLUMES of Pap smears face different management challenges. One of these is staffing enough cytotechnologists to handle increased volumes of Pap smears.

The economics of using automated screening is different for these laboratories. They use TriPath Imaging's AutoPap system to expand the capacity of their laboratory, allowing it to accommodate additional specimen volumes.

In this case the 25% archive rate of the AutoPap (see page 12) translates into a 33% improvement in capacity. Large laboratories, such as **Unilab, Inc.** of Tarzana, California, consider expanded capacity to be one strategic benefit of using the AutoPap to perform primary screening of Pap smears. This is illustrated by the table below:

W/O AutoPap		With AutoPap	
100 slides		**133 slides**	
100 x $10	$ 1,000	133 x $5	$ 665
		100 x $10	$ 1,000
		Total Cost:	$ 1,665
Reimbursement:	$ 1,460	**Reimbursement:**	$ 1,942
Net per slide:	$ 4.60	**Net per slide:**	$ 2.08

Assumptions:

1. Reimbursement of $14.60
2. AutoPap charge of $5.00
3. Conventional Pap screening of $10.00
4. Considers only screening costs

Lab Industry Briefs

AD AGENCIES PREPARING "DIRECT TO PATIENT" MARKETING CAMPAIGNS

HERE'S MORE EVIDENCE that healthcare providers like laboratories and pathology groups will increasingly market their services directly to consumers.

One of the largest consolidated advertising agencies in the world has taken minority equity positions in five healthcare-related Internet companies. **Omnicom Group**, whose agencies include **BBDO Worldwide** and **DDB Worldwide**, expects to use these relationships to connect its pharmaceutical company clients with both consumers and physicians. Two sites are consumer-oriented (**Healthology Inc.** and **Caresoft Inc.**); two sites are physician-oriented (**WorldMedicalLeaders.com Inc.** and **eMedicine.com Inc.**); and one is a clinical trials site (**eResearch Technology Inc.**).

Omnicom Group hopes to capture the identities of consumers and physicians who visit these Web sites. "We will be able to give [drug companies], down to patient and doctor, the kind of audience they want. We're going to be able to cut this so many different ways. They must go through us," stated Tom Harrison, chief executive of Omnicom's diversified services division.

The involvement of an advertising agency in the equity ownership of these e-health companies has generated controversy. But the fact that a major global ad agency is willing to take an investment position demonstrates that use of the Internet to reach both consumers and physicians about healthcare services is expected to occur.

Alert readers will note that CareSoft owns a consumer healthcare site called theDailyApple.com. **Quest Diagnostics Incorporated** uses this Web site to permit its patients to access their laboratory test results. This is one reason why Quest Diagnostics is ahead of most of the lab industry in positioning itself to become a brand name widely-recognized by consumers.

SPECIFICATIONS FOR ELECTRONIC SIGNATURES UNDER DEVELOPMENT

MANY LABORATORIANS ARE FAMILIAR with the passage of the federal Global and National Commerce Act that establishes electronic signature standards. This law takes effect in October. However, few people understand that HIPAA requirements are more complex.

Most states already passed electronic signature legislation. The federal law establishes minimum standards for legally-binding e-signatures, but remains technology-neutral. It will supercede some state laws which have lower requirements for electronic signatures.

The standards that HIPAA proposes for electronic signatures can be found at *http://aspe.os.dhhs.gov/admnsimp*. HIPAA guidelines currently do not require any type of electronic signature, but that could change over time.

HIPAA requirements say that if users, like laboratories, want to use electronic signatures, their system must include user authentication, feature non-repudiation, and guarantee the integrity of the message or data to which it is "attached."

A number of vendors are working to establish a viable e-signature system. These include **Verisign** (California), **Silanus Technology** (Quebec), and **RSA Security** (Massachusetts). TDR

Dark Index

National Anatomic Pathology Companies Continue to Grow

Local pathology practices have a template upon which to base their own growth strategies

IT'S BOOM TIME IN ONE SEGMENT of the clinical laboratory world. The national anatomic pathology companies are posting record rates of growth and profits.

The sustained and strong financial performance at **DIANON Systems, Inc.** and **IMPATH, Inc.** has not gone unnoticed by Wall Street. Share prices for the two companies have zoomed steadily upward since January.

At DIANON Systems, second quarter revenues and net income skyrocketed by 28% and 66%, respectively. Revenues went from $19.1 million in Q2-99 to $24.4 million in Q2-00. Net income went from $0.9 million to $1.6 million during the same period.

DIANON's stock now trades around $42 per share. Last fall, it was as low as $9 per share. The company predicts it will sustain a 25% growth in revenues through 2001.

New Pathology Products

DIANON's new product is a hepatitis testing service for gastroenterologists. Called HepProgramT, it offers a comprehensive menu of immunologic, chemistry and esoteric molecular genetic assays packaged to meet the specific needs of gastroenterologists.

The company is offering this new testing package to the 1,000 gastroenterologists who currently are its clients. But DIANON is also pointing its sales force to the remaining 7,500 GI specialists who currently send no specimens to the company.

At IMPATH, revenue and earnings growth were equally strong. Second quarter revenues and net income increased 60% and 34%, respectively. The change in second quarter revenues was from $20.8 million to $33.4 million. Net income similarly climbed from $2.3 million to $3.1 million.

Stock Split At IMPATH

Investors have boosted IMPATH's share price up from $14 in January to $43 recently. IMPATH did a stock split on August 29. Following the split, its share price remained in the low $40s.

But the more interesting story at IMPATH is that sales of its pathology-related services are picking up. IMPATH used clinical data generated from its AP caseload to create drug discovery and development tools. Revenues from these services are steadily climbing.

IMPATH's efforts to package anatomic pathology data into added value products and services provides pathologists with a business template worth studying. The company is attempting to convert individual case data into useful clinical knowledge that has widespread application within the medical, research, and pharmaceutical communities. These product exten-

sions allow it to generate additional profits from its core clinical services.

Although different in the way it services its widespread regional markets, **AmeriPath, Inc.** also reported strong gains in net revenue. Revenue increased 33%, to $55.4 million between Q2-99 and Q2-00.

Individual Path Practices

But AmeriPath, as a pathology physician practice management company, is the cumulative total of its individual pathology practices. Writedowns related to an AmeriPath pathology group in Cleveland caused net income to decline from $5.7 million in Q2-99 to $3.0 million in Q2-00.

For the anatomic pathology profession, the sustained multi-year success of DIANON Systems and IMPATH carries several important messages. First, these companies demonstrate that anatomic pathology (AP) services, particularly cases referred from outreach physician offices, represent a profitable and easily-grown business opportunity.

Second, investment in a professional sales and marketing program can generate steady revenue growth for pathology group practices. This is profitable new anatomic pathology business.

Solicit From Out-Of-Town

Third, the competitive marketplace for anatomic pathology services is evolving and becoming more complex. This has two consequences. It means that clinicians are learning to expect more sophisticated services from their AP provider. It also means that anatomic pathology groups that refuse to evolve with this changing market may find themselves outflanked by nimbler AP competitors from out of town.

THE DARK REPORT considers the business and financial performance of DIANON Systems and IMPATH to be worth the study of local pathology groups. Healthcare remains a "local business." Thus, national AP companies work at a disadvantage when, as out-of-towners, they enter local markets and solicit biopsies from physicians practicing in the area.

Local pathology practices have an inherent competitive advantage against the national AP companies. Most local groups are hospital-based. Over the years, their pathologists have forged strong personal relationships with the clinicians practicing at these local hospitals.

This gives pathologists an important head start against sales reps representing national AP companies. First, local pathologists have pre-existing, even long-standing personal relationships with the physicians in their community. Second, their relationship is a doctor-to-doctor relationship, not a sales rep-to doctor relationship.

Local Physicians

THE DARK REPORT observes that specimens which fuel the rapid growth of DIANON Systems and IMPATH come from local physicians in communities throughout the United States. Generally, these are specimens which formerly went to the anatomic pathology group practice based in the nearby hospital.

For this reason, hospital-based anatomic pathology group practices should see the national AP companies as both a threat and an opportunity. The threat is the loss of local specimens, and the revenues associated with them, as sales reps of the national AP firms convince local doctors to do business with their company.

The opportunity is for hospital-based pathology groups to invest in professional sales and marketing programs. Such programs will deliver a steady growth in revenues, profits, and most importantly—partnership income distributions—to pathologists with the foresight to protect and expand their local market. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Here's an interesting rumor. The September 11 issue of *Business Week* magazine says that **Abbott Laboratories Inc.** may acquire **Beckman Coulter, Inc.,** based in Fullerton, California. *Business Week* quoted a financial analyst who believed the rumor was true. Since this rumor became public, spokesmen for both Abbott and Beckman Coulter declined to make any comment on the veracity of the *Business Week* story.

ROCHE INVESTS IN TRIPATH IMAGING

Pharmaceutical manufacturer **Roche** is making a $40 million capital investment in **TriPath Imaging, Inc.** of Burlington, North Carolina. TriPath manufactures the PREP® and AutoPap® devices for automating Pap smear preparation and screening. For TriPath, Roche's investment is a big vote of confidence in both its products and its potential for future growth. Roche will own 24% of TriPath. Roche also owns 49% of **Laboratory Corporation of America**.

IS THERE A GROWING DIABETES "CRISIS" IN THE U.S.?

During the 1990s, the incidence of diabetes increased 33%, according to a study published in the September issue of *Diabetes Care*. Between 1990 and 1998, the share of the population found to have diabetes climbed to 6.5%. Among people 30-39, diabetes rates increased by 70%! Dr. Frank Vinicor, Director of the **Center for Disease Control and Prevention's** diabetes division, says that increased obesity among the population is responsible. The study is an annual telephone survey in which people are asked if they have diabetes. Because of the link between obesity and diabetes, researchers expect to see an increased incidence of diabetes among Americans.

MORE ON: DIABETES

This ominous trend will stimulate new diagnostic and prognostic test assays for diabetic patients. Clinical laboratories and pathology group practices which develop specialized expertise in diabetes detection and disease management will probably have high demand for their services in coming years. What is particularly interesting is that, among people only 30-39 years old, the rate of diabetes has increased 70% in just eight years. This is a significant change in the usual demographics of the disease.

DOCS TAKE TO INTERNET

Here's interesting evidence that doctors are ready to embrace Internet-based services, including clinical laboratory and anatomic pathology. A radiologist, Philip Berman, M.D., created **AuntMinnie.com** into a "radiology portal extraordinaire." He purchased a competitor, **Radiologybiz.com** to maintain his market dominance. Radiologists submit a free registration and can then access free search engines, equipment auctions, and so forth. Most popular features are vendor catalogues, CME calendars, and archived articles. In seven months, Dr. Berman's site signed up 16,000 of the nation's 22,000 radiologists!

That's all the insider intelligence for this report. Look for the next briefing on Monday, October 2, 2000.

THE DARK REPORT

UPCOMING...

- *The Good, the Bad, and the Ugly of Hospital Pathology Part A Contracts.*
- *New Kind of Laboratory E-commerce Service Provides Look at the Future for Lab Testing.*
- *Trouble in River City: Why One Consolidated Hospital Laboratory Floundered in the Midst of Success.*
- *Slashing Costs in the Hospital Laboratory: Five Innovative Lab Directors Share Their Management Secrets.*