Volume XV, Number 11 Monday, August 18, 2008

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Two Healthcare Trends Collide on These Pages

THIS ISSUE OF **THE DARK REPORT** YOU NOW HOLD IN YOUR HANDS demonstrates the perfect intersection of two trends. One trend, transparency in health outcomes and a public expectation of reduced medical errors, is a direct threat to laboratories which fail to deliver high-quality and accurate lab test results. The other trend is the way quality management systems (QMS) are being "pulled" into laboratory operations and healthcare.

This first trend is analyzed on pages 16-18, where you will read how the widely-publicized deficiencies of several labs and pathologists in Canada has become a public issue. To bolster public confidence in laboratory testing, pathologists with the **Canadian Association of Pathology** (CAP) are creating a voluntary proficiency testing program. It is starting with breast cancer testing for estrogen receptors (ERs) and progesterone receptors (PRs). As an interesting side note, Canada's single-payer model health system has yet to step forward and pay for this proficiency testing program.

The second trend—involving the use of quality management systems, including "ISO:15189 Medical Laboratories"—is assessed on pages 3-5. This is one of the lab industry's first alerts to this emerging development. Our Editor, Robert L. Michel, considers it important enough that he has assembled an impressive panel of experts to speak on QMS at the upcoming *Lab Quality Confab* on September 24-25, 2008. That promises to be a revealing series of presentations and I recommend that clinical labs and pathology groups already confronting use of quality management systems be present at this unique event. First, it is not likely that this same assemblage of experts on ISO:15189 and similar quality management systems will be gathered at one time and place again soon. Second, Robert has a knack for pulling together a spectrum of experts, who, collectively, deliver an amazing amount of information and unmatched strategic wisdom. That's a lot of bang for your buck!

I will also step forward with another recommendation. I suggest that you use the two intelligence briefings referenced above as discussion points for a strategic session in your laboratory or pathology group practice. I'll bet that, as your leadership team talks through the implications of trend one—outcomes transparency and public expectations—and contrasts that with trend two—use of QMS to continuously improve quality, productivity, and performance—it is going to agree on some surprising new directions for your laboratory. TDR

First U.S. Labs Nearing ISO:15189 Accreditation

ISO:15189 likely to influence upcoming reform and revisions to CLIA licensing requirements

CEO SUMMARY: Laboratories, hospitals, and other healthcare providers in the United States will increasingly be required to adopt quality management systems (QMS) as part of their regular operational routine. This is consistent with trends in other developed countries. Several U.S. laboratories are in the process of gaining accreditation under "ISO:1519 Medical Laboratories." These developments will be discussed at the upcoming* Lab Quality Confab *in Atlanta next month.

By Robert L. Michel

WITHIN THE NEXT 12 WEEKS, it is likely that the United States will have its first ISO:15189–accredited laboratory. As you read this, three laboratories in the United States are making steady progress toward accreditation under ISO:15189 Medical Laboratories.

It is likely that few pathologists and laboratory managers will take notice of this fact. Yet, the first ISO:15189 accreditations in the United States will be a significant event for this country's laboratory industry.

That's because ISO:15189 has the potential to shoehorn its way into the laboratory licensure and accreditation structure in the United States. To be sure, this won't happen overnight. But there are powerful forces at work in healthcare and laboratory medicine that have one thing in common: providers, including laboratories, hospitals, and even physician groups, will need to use quality management systems (QMS) to maintain accreditation, licensure, and eligibility for reimbursement.

In fact, odds are good that the impending reform and updating of CLIA (Clinical Laboratory Improvement Act) standards will include a requirement that, to maintain status as a CLIA-licensed laboratory, the candidate laboratory must demonstrate its effective use of quality management systems in its daily operations. Officials from CMS have stated publicly that their intent is to incorporate use of quality management systems into the next generation of CLIA requirements.

For that reason alone, laboratory directors and pathologists in the United

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. **(ISSN 1097-2919.)**

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

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

States will want to pay closer attention to quality management systems. Within just a few years, renewal of their laboratory's CLIA license will probably require effective deployment and use of a quality management system.

Even if the concept of a quality management system (QMS) is new to most lab directors and pathologists, it has been around for more than 12 years in the medical device industry. In 1996, a new federal law and supporting regulations took effect. Medical device manufacturers, including *in vitro* diagnostic companies, must use good manufacturing practices (GMPs) and follow the Quality System (QS) requirements of the **Food and Drug Administration** (FDA). This is an example of how quality management system requirements are already working their way into healthcare regulatory requirements here in the United States.

On the ISO:15189 front, THE DARK REPORT is aware of two organizations currently offering this accreditation to help laboratories. One is the **American Association for Laboratory Accreditation** (A2LA), based in Frederick, Maryland. The second is the **College of American Pathologists** (CAP), located in Northfield, Illinois. *(See TDR, March 3, 2008.)*

➤Secretariat For TC 212

Another laboratory organization that has both long experience and deep involvement in quality management systems is the **Clinical and Laboratory Standards Institute** (CLSI) in Wayne, Pennsylania. It has the unique honor of being the Executive Secretariat for Technical Committee 212 (TC 212) of the **International Standards Organization** (ISO). TC 212 is responsible for developing and publishing more than 20 ISO standards relating to medical laboratories and IVD products, including ISO:15189. *(See TDR, June 16, 2008.)*

Because of these unique perspectives, Glen Fine, CLSI Executive Vice President and Chief Staff Officer, will speak at the upcoming *Lab Quality Confab* on how quality management systems are driving major changes in laboratory accreditation and licensure, both here in the United States and globally. *Lab Quality Confab* will take place in Atlanta, Georgia, on September 24-25, 2008.

➤Contribution To Lab Success

Because of the growing contribution of quality management systems to the successful operation of clinical laboratories and pathology group practices in the future, there will be other important presentations at *Lab Quality Confab* on quality management systems in general and ISO:15189 Medical Laboratories in particular.

For example, since 2003, Canada's Ontario Province has mandated that laboratories must be accredited under ISO:15189. By year end, more than 200 laboratories in Ontario will be ISO:12589–accredited. To share the lessons learned from the accreditation process, Ruth Jaeger, General Manager, **Eastern Ontario Regional Laboratory Association** in Ottawa, will make a presentation at *Lab Quality Confab.*

Following this session, attendees will hear from one of the first laboratories in the United States actively working to achieve ISO:15189 accreditation. At **Piedmont Medical Laboratories, Inc.**, of Winchester, Virginia, Benita Haines, Quality Management, Compliance & Education Coordinator, will explain why the laboratory made the decision to become ISO:15189–accredited and share the lessons it is learning.

Another tool of quality management systems that is already a requirement for hospitals—and may be incorporated into laboratory licensing requirements—is FMEA (Fault Mode and Effects Analysis). Since 2005, **The Joint Commission** has required hospitals to conduct at least one FMEA project each year. From **Abbott Diagnostics** of Abbott Park, Illinois, Tina

Krenc, Director, Diagnostics R&D Phase System, will be at *Lab Quality Confab* to explain FMEA and FTA (Fault Tree Analysis). These are established systems used to identify, in advance, sources of systemic failure and risk in an organization's work flow and individual work processes.

Since QMS is also working its way into laboratory proficiency testing (PT), *Lab Quality Confab* will feature a presentation on that topic by Michael Noble, M.D., FRCPC, Chair, Program, Office for Lab Quality Management, **University of British Columbia**, Vancouver, British Columbia. Because of widely publicized lab testing deficiencies that surfaced in recent years in Canada, Noble's first-hand experience at developing proficiency testing programs that address quality problems will be of particular interest. *(See pages 16-18 in this issue.)*

Spotting Trends Early

Our long-time clients and readers know THE DARK REPORT has a credible track record at being first to identify many important trends in laboratory management, often in their earliest stages. Armed with that knowledge, labs and pathology groups have had the time and foresight to establish winning strategies in response to these trends.

It is happening now with quality management systems. This trend is in its early phase, giving lab managers and pathologists time to develop strategies and effective responses. Adoption of quality management systems will move forward at a steady pace, particularly as regulatory bodies incorporate QMS into licensing and accreditation requirements.

The collection of speakers and presentations on QMS at *Lab Quality Confab* will be the first time that so many primary players will be together at one time to discuss this topic. That makes it a unique opportunity for lab leaders to get the full picture, as well as to meet and network with these experts.

Quality Management Systems Coming to Lab Profession

MANY LAB DIRECTORS AND PATHOLOGISTS remain unaware of quality management systems (QMS) and the role these organizational tools have in transforming how healthcare organizations, including laboratories, conduct their affairs.

Wikipedia defines quality management sytems "as a set of policies, processes and procedures required for planning and execution (production / development / service) in the core business area of an organization. QMS integrates the various internal processes within the organization and intends to provide a process approach for project execution. QMS enables the organizations to identify, measure, control and improve the various core business processes that will ultimately lead to improved business performance."

For laboratory managers, the key insight is that quality management systems are, by design, a comprehensive methodology that requires laboratories and other organizations to be operated with a specific philosophy. Additionally, with hospitals, laboratories, and other healthcare providers being asked to produce products and services where defects and errors are measured in events-per-million, quality management systems have the tools, methods, and capabilities to help organizations achieve these remarkable levels of quality.

A final word on the arrival of quality management systems into laboratory operations. With the emphasis on improving patient safety, reducing medical errors, and improving quality, labs cannot rely on the management methods of the 1980s and 1990s. It is no coincidence that Lean, Six Sigma, ISO:15189, and other approaches are gaining acceptance in the laboratory profession. Labs are already using these methods to achieve levels of productivity and quality unimagined just a few years ago. **TDR**

Independent Labs Won't Get Medicare PQRI Bonuses

➤Independent labs learn they will not get same Medicare PQRI payments as other pathologists

➤➤CEO SUMMARY: Medicare does not intend to make bonus payments this year to independent labs currently reporting quality information for breast and colon cancer cases. The federal claims payment system is unable to pay independent labs for participating in the federal physician quality reporting initiative (PQRI). But physician pathology groups participating in PQRI will receive the bonus payments as expected. CMS has yet to formally acknowledge this problem, leaving labs with unanswered questions.

OVER THE PAST FEW WEEKS, independent laboratories have learned they will not get any bonus payments this year under the new federal Physicians Quality Reporting Initiative (PQRI). Bonus payments for next year also are in question. Pathology physician groups, however, will get their bonuses under the program.

Officials from the federal **Centers for Medicare & Medicaid Services** (CMS) have yet to publicly explain why independent labs are being excluded. THE DARK REPORT left messages with CMS officials last week seeking comment, but, as of press date, no one from CMS had responded.

➤Independent Labs

By some estimates, independent labs represent only about 12% to 28% of all labs. But officials at **Pathology Service Associates, LLC**, (PSA) a company in Florence, South Carolina, that does revenue cycle and business management for pathologists, say independent labs make up about 60% of their 500 lab clients nationwide. PSA officials could not estimate how much money independent labs stand to lose as a result of not getting Medicare PQRI bonus payments this year.

John Outlaw, CHC, PSA's Chief Compliance Officer, who has investigated the problem, explained that the problem relates to the fact that CMS treats independent laboratories as suppliers rather than physicians. "Therefore, for claims from independent laboratories, although CMS has the quality code for each of these cases, it does not have the 'rendering physician' information it needs to determine which physician is eligible for the PQRI bonus," he said.

"CMS didn't see this coming," Outlaw added. "They found out about it after they built all their PQRI reporting tools into the physician claims-adjudication logic. It never occurred to them that a substantial portion of claims would come from independent labs and go down a separate claims processing route.

"At this point, CMS can't do anything about it without incurring significant expense to rewrite their claims-adjudication systems," Outlaw said. "We hoped that CMS would develop some alternative reporting measures, but from what we can

tell, it looks like CMS will not develop a solution to this situation."

Beginning late last year, pathologists nationwide scrambled to get the requisite paperwork in order to participate in Medicare's voluntary PQRI. Most pathologists believed the effort was worthwhile because Medicare officials had said all participating pathologists that met certain quality reporting requirements would earn a bonus of 1.5% of their total Medicare billings for the year.

For PQRI reporting in 2008, CMS had designed two pathology-focused quality measures that relate to breast and colon cancer cases. The 2008 PQRI bonus was designed to be based on labs reporting quality measures and not on actual compliance with quality standards. The quality measures required labs to modify their reporting, documentation, and coding protocols. Bonus payments of as much as 1.5% of total Medicare allowed charges (not just those for the quality measures) were due to pathologists that successfully reported quality measures for 80% of their eligible breast and colon cases.

PQRI Bonus Calculations

In a memo to its client pathologists last December, PSA said, "It is important to note that the participation is measured by each individual physician as opposed to each practice; this is true for both computing the 80% as well as payment of bonuses on total Medicare allowed charges. Further, based on PSA data, it appears, that relatively few cases will actually be eligible for reporting which means, proportionately, the work to enhance coding and documentation on the select cases in order to garner additional payment on all Medicare cases should yield a nice return on investment."

This past spring, officials at PSA and at other organizations that represent pathologists began asking CMS officials about the PQRI program. PSA said CMS has recently indicated on its Web site that physicians employed by independent laboratories will not be included in the PQRI program. It is important to note, however, that except for this mention on the Web site, CMS has made no formal statement about the status of independent laboratories in PQRI.

CMS Statement

On its Web site, CMS said the following: "Independent Laboratories (ILs) are a supplier specialty (69), not a physician specialty. The rendering provider field (24J) on the CMS-1500 claim is not valid for IL claims in the billing methodology for ILs. Because the statute authorizing PQRI requires analysis of reporting and allowed charges at the level of the individual professional, pathology services billed under IL rules are not able to be considered in PQRI analyses. Reference: http://www.cms.hhs.gov/pqri."

THE DARK REPORT observes that CMS has painted itself into an interesting corner. These developments are evidence that officials within CMS do not fully understand how laboratory testing services are organized and delivered.

By incorporating several pathology procedures into the Medicare PQRI reporting and bonus program, CMS was recognizing the value of anatomic pathology services and how they contribute to improved quality and better patient outcomes. But, by not developing a system to allow PQRI reporting from pathologists working in independent labs to earn the same bonus payments as pathologists working in physician group practices, CMS has once again put itself at odds with the laboratory profession.

First, CMS is again creating ill will with a segment of the pathology profession, by discriminating against pathologists working in an independent laboratory. Second, since independent labs won't get PRQI incentives, CMS is not likely to get information from these sources going forward. That will skew interpretation of the pathology data it does collect. **TDR**

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MT/MLT Distance Learning Goal of Collaboration

➤ ARUP and Weber State team up to make it easier for interested lab staff to advance skills

➤➤ CEO SUMMARY: To encourage more students to pursue medical technology (MT) and medical laboratory technician (MLT) degrees, ARUP Laboratories and Weber State University (WSU) are collaborating to promote the distance learning programs offered at WSU. Online students can work any shift and take courses anytime (day, night, or on weekends), thereby making education more accessible to prospective students. Distance learning is likely to be an important source of education for new technical staff for labs.

THERE IS AN ELEPHANT IN THE ROOM at every lab industry gathering: the existing—and growing—shortage of trained technical staff. Looming over this existing labor gap is the impending retirement of the baby boomer generation from the nation's laboratories.

Many labs report an absolute inability to recruit, hire, and retain adequate numbers of medical technologists (MTs) and medical laboratory technicians (MLTs) to meet existing needs. Over the past five years, THE DARK REPORT has identified and told the stories of how innovative laboratories and hospitals are increasing funding for MT and MLT training, along with the growing use of long distance education where local programs do not exist.

Now comes news of another credible, ground-breaking effort to increase the supply of MTs (also known as clinical laboratory scientists or CLSs), MLTs (also known as clinical laboratory technicians or CLTs), and other technical positions. On July 30, 2008, **ARUP Laboratories** and **Weber State University** (WSU), announced a "personnel education collaboration" that will combine Weber State's distance learning education programs with ARUP's efforts to promote distance learning among its own laboratory staff and that of its client laboratories.

Both organizations are located in Utah. ARUP is based in Salt Lake City at the **University of Utah**, and Weber State is located in Ogden. WSU was the first university to offer a complete CLS bachelor's degree and CLT associate's degree online. As part of the agreement, the $95 distance-learning program application fee will be waived for any applicant referred through ARUP and its Web site.

➤ Distance Learning Goals

This collaboration is significant because it is marketplace recognition that the best short-term solution to training more technical staff will be long distance learning programs. "We estimate that currently, educational programs in the United States produce fewer than half of the necessary laboratory personnel needed by our nation's clinical laboratories," explained ARUP President and COO Ronald L. Weiss, M.D., MBA. "These shortages are becoming more critical within commu-

nity health systems that operate growing laboratory outreach programs. We hope that our collaboration with Weber State provides client laboratories with an opportunity to educate laboratory personnel, without taking them away from their work sites."

How Distance Learning Works

To make distance learning succeed, students need to perform clinical work in their own laboratories. "Students access the courses online anytime," said Yasmen Simonian, Ph.D., MT(ASCP), CLS(NCA), WSU's Dean of the Dr. Ezekiel R. Dumke College of Health Professions. "Completion of laboratory competencies for each course occurs after work in their own facilities with approval and support of their employers.

"Rather than traveling to off-site classes, students who participate in this online program will use the resources of their respective work facilities to successfully complete required laboratory competencies," she added. Simonian is a former Professor and Chair of the Department of Clinical Laboratory Sciences.

Weber State has offered its on-campus program in clinical laboratory sciences for 32 years. The online degree program was launched in 2001. Each year, about 75 students graduate from the department's online and on-campus programs. Since 2001, the department has graduated about 157 students from its online program. Some 550 students are currently taking online courses at WSU in either the department's two- or four-year programs.

Started Seven Years Ago

"Seven years ago we started the online program for four-year students with the help of ARUP and **Intermountain Health Care** (IHC) in Salt Lake City," Simonian explained. "Both IHC and ARUP had problems attracting people to work in rural Utah. So, we thought, if students can't come to us, we'll go to the students. What we offer online is accredited by the **National Accrediting Agency for Clinical Laboratory Sciences** (NAACLS) of Chicago, Illinois, and parallels our on-campus offerings."

"Like other laboratories, ARUP feels the impact of the staffing shortage," commented Weiss. "It's a difficult time for laboratories attempting to fill medical technologist positions. It's a problem here and we know it's a problem on the national level. Distance learning has helped us. Last year, we hired 116 medical technologists or med tech equivalents, and we hired 103 technologist trainees. We see how the opportunity for distance learning gives more students the ability to advance their laboratory skills and career.

"By working with client labs to offer this program to their employees and to waive the processing fee, we hope that these efforts will serve as a tipping point for some people to make that decision and enroll in these programs," Weiss said. "Labs have to face the staff-shortage problem in creative ways if laboratory medicine is to accommodate the growth in test volumes and the new diagnostic technologies that are in our future."

Education Opportunities

At the start of the 1990s, there were about 500 accredited laboratory science programs nationally. During the balance of that decade, there was a steady decline in the number of such training programs. That left many cities without any MT/MLT training programs locally. Currently, NAACLS lists 222 educational programs nationwide for CLS/MTs, and 205 education programs for CLTs/MLTs.

Distance learning is likely to play a major role in meeting the labor supply gap, as the number of local MT/MLT training programs in this country is not likely to increase significantly in the next few years. **TDR**

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NEWSMAKER INTERVIEW

Successful Laboratories in the Future Will Brand Themselves, Add Value

"There is an opportunity for the laboratories to become more proactive with health plans. Pathologists are reading the literature and know specifically which diagnostics tests should be performed before expensive imaging procedures are ordered." —Kerry Kaplan, *President, Healthcare Connections*

➤➤ ***CEO SUMMARY: At the most recent* Executive War College, *Kerry Kaplan, President of Healthcare Connections in Natick, Massachusetts, discussed the results of his national survey of managed care executives. In part one of this interview, Kaplan described the results of his survey, along with advice on how laboratories can build a positive, ongoing partnership with local managed care plans. In part two, he explains what steps pathologists and lab directors can take to become partners with their health plan customers to improve the delivery of healthcare. He also explains how labs have an opportunity to work more closely with payers that are interested in saving money on complex, expensive cases. Kaplan ends by stressing the need for labs to have a branding strategy.***

PART TWO OF TWO PARTS

EDITOR: In part one of this interview, we discussed the results of your informal survey of managed care executives. Conducted prior to the *Executive War College* last May in Miami, you interviewed nine health plan executives to learn how they viewed laboratory services and what labs should know about the changing needs of health insurance plans. You explained that health plans are generally disappointed with what they get from the clinical laboratories with which they work. *(See TDR, July 28, 2008.)* Let's start part two by discussing why, in today's managed care contracting environment, lowest price seems to be the main bargaining chip. How does a lab shift the discussion to value?

KAPLAN: This cuts directly to the key issue. It's a fact that, in any industry, lowest price is not a winning strategy in the long term. If a company gets the business only because it offered the lowest price, it will lose that customer the first time another company comes along and offers that customer a cheaper price. The winning strategy is to offer a competitive price combined with value that competitors can't match. That helps retain the customer over the long term.

EDITOR: This was the point you made in part one, relative to the comments made at the 2007 *Executive War College* by David King, the Chairman and CEO of **Laboratory Corporation of America**.

KAPLAN: In simplest terms, during his remarks, King said that laboratory services have become a commodity item with most managed care companies. That comment was not popular with some listeners in the audience, who overlooked the fact that King was discussing the need for a laboratory to have a value proposition to earn additional reimbursement. His point was, that for a laboratory to win contracts on any factor other than lowest price, the lab must learn how to provide added value to its health plan customer.

EDITOR: Do you have an example?

KAPLAN: As we discussed in part one, laboratories must become a partner with health plans and help them achieve two goals. First, the lab must play a role in lowering the health plan's costs. Second, labs need to recognize how health plans are adopting protocols based on evidence-based medicine (EBM). Labs can then help health plans achieve improved outcomes for beneficiaries.

EDITOR: Was this a finding in your survey?

KAPLAN: Yes. The managed care CEOs and medical directors all told me that there is a significant new opportunity for labs to participate in helping payers to develop these EBM protocols. Even better, this opportunity is growing in both importance and influence. Those physicians who were at the forefront of EBM 10 years ago acknowledge that we currently apply these protocols to about only 4% of clinical decisions.

EDITOR: It makes sense that labs would have a significant opportunity in this area, because laboratory testing underpins many protocols for diagnosis and treatment.

KAPLAN: That's exactly what we learned from the managed care executives we interviewed.

For example, they all had examples where laboratory tests must first be performed before the doctor orders any expensive imaging. My guess is that, on average, physicians only order those lab tests about 55% of the time before they authorize high-cost imaging tests they want done for their patients. Further, because of a published **Rand** study, we know that, when you see a doctor in this country, you get the appropriate treatment only about 55% of the time. *(See TDR, July, 7, 2003.)*

EDITOR: This is an interesting direction for pathologists and laboratories.

KAPLAN: That's because it is an opportunity for the pathologists and laboratories to become more proactive with health plans. Pathologists constantly read the current literature and know specifically which diagnostics tests should be performed before expensive imaging procedures are ordered. Take the example where a pathologist knows: one, the indications for particular patients; and, two, knows the proper test is being done only about half the time before the imaging is ordered. That's an opportunity for that pathologist to meet with the medical director of the managed care plan and ask, 'Do you notice what we notice?' Once you ask that question at the medical director level, you're operating as a partner with the health plan.

EDITOR: That's a different approach for labs. But pathologists are very sensitive about "offending" referring clinicians by commenting on ways to improve lab test ordering patterns. So conversations with payers on these ways to improve adherence to clinical guidelines seldom occur for precisely that reason.

KAPLAN: I acknowledge that concern. However, laboratories don't need to remain totally silent about opportunities for the health plan to implement EBM guidelines that benefit patients (who, on average, get recommended care only 55% of the time). This is an opportunity to encourage more efficient use of limited healthcare resources. Remember, healthcare is changing. Clinical habits of the 1990s will not be added-value in our evolving healthcare system.

EDITOR: That is an important point.

KAPLAN: Recognize how significant these savings can be when a laboratory has an effective partnership with a local health plan. Payers are interested in saving money on complex, expensive cases because that's where the money is. At the same time it's an opportunity for labs to help health plans cut costs and simultaneously improve quality. When doing both at once, your lab helps the health plan to deliver EBM. Now your lab is a commodity vendor *and* a partner—at the same time!

EDITOR: Are you saying that laboratories now need to pay attention to costs *and* quality standards?

KAPLAN: That's correct. Over the next generation, two factors will drive health plan decision-making. One is reimbursement, meaning what health plans pay providers, including labs. That's always been true and will continue to be true well into the future. The second factor to drive decision-making is EBM, which will guide health plans as they determine what to cover and how much to reimburse.

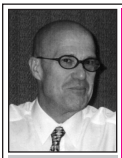
EDITOR: That's an opening which laboratories seldom consider.

KAPLAN: Which is unfortunate. As the healthcare system develops EBM guidelines and supports better clinical outcomes with pay-for-performance (P4P) incentives to providers, this plays to the strengths of laboratories. After all, laboratories produce the lion's share of the data that resides in a patient's permanent record and pathologists constantly evaluate how clinicians use laboratory tests.

EDITOR: Could you address the lab industry's opportunities in genomics?

KAPLAN: Yes. We are only now getting the earliest insights into how genomics will affect the healthcare system. That is one reason why I say the healthcare system is both imploding and exploding. We have millions

of aging baby boomers who need healthcare. Going forward they will access an ever-widening range of results from genomics tests. Yet, at the same time, all this is happening in a healthcare system that is, in essential ways, not much changed from 100 years ago—particularly in the way that guidelines tend to require everyone to be treated the same. Thus, our healthcare system will be sorely stressed to respond to genetic tests which tell us that every individual needs to be treated uniquely and differently.



Kerry Kaplan

"The answer is simple. If you meet with the medical director to discuss what's happening with genomics, then that's an example of being a partner."

EDITOR: From that perspective, your advice that laboratories become a resource for health plans makes sense.

KAPLAN: The lesson for lab directors and pathologists is that they should be on the front side—addressing the issue of how to use genomic test results appropriately—rather than on the back side. That might mean educating health plans about which tests they should cover and which ones they should not cover. I am suggesting that you reposition your lab. Don't be the lab that gets the memo from the payer saying, 'From now on we're not going to cover this test because it doesn't do any good.' Rather, be the lab that advises the health plan's medical director when he or she writes that letter.

EDITOR: This is certainly a paradigm shift in how labs think about their relationship with health plans. How can they become the laboratory that advises plans about how to write these letters?

KAPLAN: The answer is simple. If you meet with the medical director to discuss what's happening with genomics, then that's an example of being a partner. This cropped up repeatedly in our survey. One respondent said, 'The main thing we need help with is genomics.' That means labs have a significant opportunity to affect what health plan executives think about genomics.

EDITOR: It illustrates the truth that, "if you don't ask, you don't get."

KAPLAN: How many labs take the time to meet with the four health plan executives I listed earlier in part one (the CEO, the COO, the medical director, and the head of large case management) and ask such a question? That leads me next to one of the most startling responses we got to our survey. One health plan executive asked, 'Are labs willing to overlook their short-term self-interest and be more active in educating doctors about the necessity of expensive tests?'

EDITOR: That's an interesting question.

KAPLAN: What that executive said is this: 'We want providers to help us figure out what's right and wrong—regardless of short-term profits—and we are willing to reward providers for not doing certain tests if it will save us money.' That will put the burden on those lab directors who understand that their lab can make $900 on a certain esoteric test, but in terms of diagnostic or clinical usefulness, those test results are not worth $900 to the patient, the physician, and the health plan. If I tell the payer that such a test is essentially worthless, that would cost the lab its margin on that test.

EDITOR: That is a game-changer when that health plan executive asks a lab to overlook its short-term interest so that the lab can help the health plan to deliver better care. That can work, but only if the health plan will reward the laboratory for this knowledge and help it develop effective EBM guidelines.

KAPLAN: Essentially, health plans want their providers to say, 'For years, we have made a lot of money on these certain tests (or procedures or office visits) and some of these tests are not worth the money you're spending.' It's very simple: Payers want help figuring out ways to save money while also improving quality. If they don't get that help from their providers and labs, this long-standing adversarial relationship between

payers and providers will continue and nothing will change for the better.

EDITOR: One last topic I'd like to ask you about involves the growth of consumer-directed healthcare.

KAPLAN: Steady expansion of enrollment in consumer-directed health plans (CDHPs) means that the time has come for laboratories and pathology group practices to brand themselves. This branding must happen in four dimensions, with consumers and patients, with physicians, with managed care plans, and with employers.

EDITOR: Is this advice based on the trend for consumers to make their choices for physicians, hospitals, and other providers?

Kerry Kaplan

➤ **"As a consumer, I want to know why this lab is a quality provider and how convenient it is to where I live. Today, in 2008, I have no idea how to answer these questions..."**

KAPLAN: Yes! Here's an example. Recently, my doctor gave me a requisition for some lab work. First, I didn't know whether my health insurance plan would cover the full or partial cost of the testing. Second, I want to have the test performed, but I have no idea which lab companies provide services in Portland, Oregon—where I live. Third, I have no idea of whether one laboratory serving Portland has better quality services than another. Even though I am a sophisticated healthcare consumer, I don't even know where to start my search for a good lab provider in the town where I live!

EDITOR: Traditionally, laboratories have been invisible to the consumer, since they marketed directly to the physicians who order tests.

KAPLAN: I understand that. But we are moving toward a healthcare system where high deductibles and CDHPS motivate consumers to be more active in selecting—and directly paying—their providers. For that reason, laboratories must be visible to consumers and must develop brand recognition. Do I go online? Are laboratories in Portland, Oregon, listed in search engines such as **Google** and **Yahoo**? Do these laboratories have Web sites that inform me, as a consumer, about why I should use their laboratory testing services?

EDITOR: Kerry, the answer to that question is that Web queries generally produce a list of the patient collection sites operated by different labs in a city.

KAPLAN: Your answer demonstrates my point. If a laboratory has done a good job branding their clinical quality, their patient service, and other important attributes, then look what happens next time my doctor gives an order for lab tests he wants me to have. At that moment, because of branding, I know a clinical laboratory that says 'We're technically the best. There's no waiting at our lab. Call this number for immediate service.' I am ready to select this lab, and my decision is going to based on more than simply cheapest price.

EDITOR: You make a strong point.

KAPLAN: Outside of healthcare, this is basic business practice. As a consumer, I want to know why this lab is a quality provider and how convenient it is to where I live. Today, in 2008, I have no idea how to answer these questions for labs and other types of healthcare providers. Yet, in today's economy, every major industry has a significant presence on the Web. It's easy for me to go to the Internet when I'm ready to buy the best car, the best lawn mower, or the best refrigerator. With just a few mouse clicks, I have immediate access to all kinds of sources, including consumer reviews, customer satisfaction data, and price/feature comparison data. This is why I describe the American healthcare system as being perfectly poised for the 20th century. Labs and other healthcare providers are way behind the curve on their use of the Internet and building their brand.

Survey of Nine Managed Care Executives Reveals Opportunities for Labs & Path Groups

PRIOR TO LAST MAY'S *Executive War College*, Kerry Kaplan, President of Healthcare Connections of Natick, Massachusetts, did an informal survey of nine managed care executives across the nation.

The goal was gain insights about the challenges and business priorities they have going forward. It was also to find out what they would suggest that laboratories do to provide added value to health plans. In part one of the interview, the list of nine executives was provided, along with the three questions asked by Kaplan. Here are the payer's answers to his third question.

Question Three:

"ANY SUGGESTIONS TO LABS?"

- "We're really looking for the timely availability of valuable data. Can they stream information 'just in time?' We'd welcome a pilot project on that."
- "If a lab wants to approach us to help with chronic disease, improving compliance with care—we would welcome that!"
- "Labs need to standardize test results."
- "We need help to be able to identify which patients will respond to treatment."
- "We need experts to help us with evidenced-based medicine (EBM)."
- "Help us get the lab out of the hospitals, it's three to 10 times more expensive for lab tests performed in the hospital than in reference labs."
- "The main thing we need help with is genomics. It's scary."
- "Labs need to 'brand' themselves. With growing enrollment in consumer-directed health plans (CDHPs), prices will be transparent. Labs need to prove their value proposition to physicians, patients, and payers."
- "Labs need to be transparent in quality. We know labs get it wrong 30% of the time."
- "Are labs willing to overlook their short-term self-interest and be more active in educating physicians about the medical necessity and appropriate utilization of expensive tests?"

EDITOR: You are making a serious criticism of healthcare.

KAPLAN: Let me give this a more personal perspective for your clients and readers. I have veins that roll, making it hard to draw blood from me. That means I want the best phlebotomist. I know that the skills of phlebotomists fall on a bell curve, as does every group of professionals. Phlebotomy is the number one concern of this consumer and your phlebotomist is the face of your lab to me. That person is my only experience with your lab and how she or he treats me is likely to determine whether I come back to your lab or not. Period. End of story.

EDITOR: Kerry, this has certainly been a unique perspective on how health plan executives view labs and lab testing services.

KAPLAN: For those lab directors and pathologists who understand this perspective, I believe they have an unprecedented opportunity to build a successful partnership with health plans in ways that benefit patients and physicians. Not every managed care company will respond to the types of business strategies I describe. However, there will be payers that want to do the right things. So labs should be persistent in finding these health plans and developing partnerships with them.

EDITOR: Thanks for a stimulating discussion about labs and payers.

KAPLAN: Thanks for the opportunity to discuss these issues. TDR

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NEWSMAKER INTERVIEW

Kerry Kaplan

Canadian Pathologists Start PT Testing for ER/PR

➤Voluntary proficiency testing program created in response to public disclosure of test deficiencies

➤➤CEO SUMMARY: Experts point out that widely publicized episodes of lab testing deficiencies in several provinces are signs that chronic underfunding of lab testing services is a key factor in these failures. To restore public confidence in breast cancer testing, the Canadian Association of Pathologists is developing a voluntary proficiency testing system for hospital labs to improve the accuracy and reproducibility of breast cancer markers, including estrogen receptor, progesterone receptor, and other clinical IHC tests.

LABORATORIES AND BANKS SHARE ONE BUSINESS ATTRIBUTE: both businesses will fail if they lose the confidence of the public. In Canada, high-profile testing deficiencies at several lab testing sites in recent years demonstrate the truth of this long-recognized principle.

Sustained cuts in laboratory funding in Canada are believed to be a major contributing factor in the handful of lab testing failures that have been widely covered by newspapers and the media in that country. Pathologists and lab directors in Canada argue that the deep funding cuts in laboratory testing, sustained over two full decades, leave the nation's laboratories with inadequate resources to produce high-quality lab test results at all sites and at all times.

With the negative consequences of underfunding now visible to the public, Canadian pathologists themselves are taking steps to correct deficiencies in the system. However, this effort to guarantee the quality of laboratory testing faces a daunting obstacle: the lack of health system funding to support a newly-instituted laboratory proficiency testing program.

Widely publicized erroneous results for breast cancer estrogen receptor (ER) and progesterone receptor (PR) testing in Newfoundland Province recently triggered a judicial inquiry. Deficiencies and possibly inaccuracies in surgical pathology biopsy reporting in another Atlantic province, as well as in Ontario and Manitoba, triggered public alarm across Canada.

To improve the reliability of laboratory test results and to boost public confidence in the quality of laboratory test results, the **Canadian Association of Pathologists** (CAP) has endorsed a proficiency testing (PT) program for laboratories doing diagnostic immunohistochemistry, including estrogen receptor/progesterone receptor (ER/PR) tests for breast cancer.

In an interview with THE DARK REPORT, Jagdish Butany, MBBS, MS, FRCPC, and CAP President, discussed the new Canadian Immunohistochemistry Quality Control Program that is endorsed and supported by the CAP. Currently it is voluntary for laboratories in Canada and they may continue to participate in other external quality assurance programs.

"We set up the National Standards Committee/Immunohistochemistry chaired by Dr. Emina Torlakovic from the **Royal University Hospital, University of Saskatchewan**," noted Butany. "She and Blake Gilks, M.D., from **Vancouver General Hospital, University** of British Columbia, set up a Web-based program, the Canadian Immunohistochemistry Quality Control (cIQc), for proficiency testing in diagnostic immunohistochemistry that included breast cancer markers and other IHC tests. However, at this time, the entire service provided by the pathologists, technologists, and IT support are donated. We are seeking funding to sustain this PT program into the future.

"Participation in the program is voluntary at this time, but this may change in the future," he said. "The CAP National Standards Committee/Immunohistochemistry is calling for mandatory certification for all prognostic and predictive IHC tests. To obtain certification, the laboratories will need to demonstrate high levels of concordance with reference values by participation in external quality assurance (EQA) programs which provide testing samples that enable calculations of the concordance, meaning that test samples would need to include large numbers of samples to provide meaningful results. One such program is the cIQc."

In an article published in the June 3, 2008, issue of the *Canadian Medical Association Journal* (CMAJ), Butany and Kathy Chorneyko, M.D., Staff Pathologist and Assistant Medical Director for Laboratory Services at **Brant Community Healthcare System**, in Brantford, Ontario, called on provincial governments to remedy problems at overworked labs.

Inadequate Funding for PT

"Although there is some momentum for technical quality assurance programs, the Canadian healthcare system does not have a well resourced national approach to quality assurance of the analytical or professional component of anatomic pathology," wrote the authors. Not waiting for provincial health systems to respond, Butany and other pathologists developed the voluntary ER/PR proficiency program and are having some preliminary success.

"Design of an ER/PR proficiency testing program was initiated in April 2007," Butany said. "By the following July, CAP executives and the general body agreed that a committee of experts should set up a platform for the development of the national standards in diagnostic immunohistochemistry. The standards would call for mandatory certification in breast carcinoma markers IHC testing, which is facilitated by the development of the suitable national EQA.

Standards Committee

"The ER/PR proficiency testing service is now available to any hospital willing to participate," explained Butany. "Proficiency of a participating laboratory is checked against the proficiency of a central laboratory and expert pathologists who interpret the same section from the same tumor and the same patient.

"We offered this PT service at no charge because we wanted to encourage lots of participation and ensure good, reproducible, quality across the country," Butany stated. "Dr. Torlakovic has done a tremendous amount of work to get this program running. So far, three rounds of slides have been sent to her from the participating hospitals and the results are recorded and evaluated.

"Because this PT program is so new, we are working on finding the best ways to do a quick evaluation of the results and their distribution," he noted. "We are also working to provide direct interaction between experts and participants in information exchange as well as directly help-

ing participants to improve their procedures whenever necessary.

"Until now, there were no protocols or standard operating procedures (SOPs) for ER/PR testing," Butany said. "Every lab seemed to do things differently. There was no consensus as to the best way to handle these tissues and ER/PR testing requires more than 40 steps. Would it matter if the surgeon took the biopsy out and kept it in the OR for two hours? Would it make any difference if the biopsy specimen stayed in the lab overnight or over the weekend without being fixed?

"Of course, we now know that each of those steps makes a phenomenal difference," he added. "National and international guidelines need to be developed, and we are supporting this movement by our own efforts. The existence of protocols will make a significant difference because all of the proper steps are bundled into the SOP. At the end, the results should be reasonably similar and reasonably reproducible. We are going one step further to establish that each pathologist interprets these slides the same way. We hope that these efforts will result in numerous new safeguards that will ensure quality reporting in prognostic and predictive IHC testing.

Regular Use of SOPs

"Pathologists recognize that SOPs are needed for every test," Butany continued. "SOPs exist for routine staining. However, immunohistochemistry tests were not fully standardized because of their complexity and much work is needed to achieve this goal.

"For example, there are different types of IHC tests," he explained. "ER/PR is a category 2 test, since the results are 'standalone' and reported independently of other evaluated parameters, but inform the oncologist whether the patient may be a suitable candidate to get a particular treatment, and what treatment is likely to be most appropriate.

"Because category 2 tests have a direct impact on the treatment choices, the quality of the testing procedures makes a tremendous difference," he emphasized. "If the specimen is processed and the quality is not excellent and not reproducible, then that laboratory has a problem which can have a negative impact on patient care. After ensuring the quality of the ER/PR tests, plans are for Dr. Torlakovic's committee to establish SOPs for all the other immunohistochemistry tests.

"In the end, it is worth noting that these highly publicized problems have been found in only one laboratory in the country, and that only a very small number of pathologists (three out of about 1,200) have had their diagnoses challenged," Butany said. "All Canadian laboratories have a major commitment to quality assurance and pathologists continue to do excellent work, in spite of seemingly insurmountable odds."

Lessons for United States

The events unfolding in the Canadian laboratory system are instructive and relevant for lab directors and pathologists in the United States. After all, underfunding of laboratory testing services in the United States has been a feature of both public and private payer policies for almost two full decades. At some point, under-reimbursement of laboratory services will trigger lab testing deficiencies that affect patient care in a noticable way.

Thus, as cracks in the performance of Canada's laboratories become visible and are attributed to sustained underfunding for lab testing services, it helps healthcare policymakers in the United States understand how underfunding of lab services here in in this country could contribute to declines in the accuracy of laboratory testing, resulting in declines to both patient care and outcomes. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There's a new lab company in New York City. **Manhattan Physicians Laboratory, Inc.** (MPL) was recently launched by two former executives from **Quest Diagnostics Incorporated**. Thomas Golubic is MPL's President and William Nouri is Vice President and Lab Operations Director. Both executives worked at Quest Diagnostics for 20 years. Last month, MPL disclosed that it had acquired **Genatom, Inc.**, a laboratory in Roseland, New Jersey, that provides clinical lab services to clients in New York, New Jersey, Pennsylvania, and Delaware. **Trevi Health Ventures** is providing MPL with approximately $20 million in venture capital funding.

NEW BLOOD TEST FOR COLORECTAL CANCER

GeneNews Limited, a company in Richmond Hill, Ontario, Canada, announced its new blood-based molecular test for colorectal cancer. Called ColonSentry, the test assesses a patient's risk of having colorectal cancer by identifying patients who are asymptomatic but who might benefit from more invasive diagnostic testing, such as colonoscopy. By analyzing a blood sample, the test evaluates the mRNA expression of a panel of seven specific genes by quantitative reverse transcription polymerase chain reaction (RT-PCR). This new test is another example of how new diagnostic technologies are able to utilize different types of specimens, such as blood, to detect cancer.

CALIF. REGULATORS SEND COMPLIANCE LETTER TO DNA DIRECT

On July 31, **DNA Direct** of San Francisco, California, announced it had received a letter from the **California Department of Public Health** (CDPH) stating that it is operating in compliance with state laboratory law. The letter said DNA Direct's tests are performed: 1) only with a physician order, 2) are conducted at licensed laboratories; and 3) that DNA Direct gives validated interpretations of results directly to individuals ordering the tests. In recent months, state regulators in California and New York have taken steps to control genetic testing offered to consumers by Internet-based companies. *(See TDR July 7, 2008.)*

TRANSITIONS

• George Poste, D.V.M., Ph.D, F.R.C. Path, F.R.S., was named Non-Executive Vice Chairman and Chief Scientific Advisor of **CDX Holdings** and Non-Executive Chairman of **CMDx** on August 1. CDX Holdings, of Irving, Texas, is a new company that is the parent company of **Caris Diagnostics** (Caris Dx) and **Caris Molecular Diagnostics** (CMDx). Poste has been a director of Caris Dx since 2006.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...anatomic pathology condo lab operator **UroPath, Inc.'s** sale to **HealthTronics, Inc.** of Austin, Texas, in a deal valued at $7.5 million. Medicare anti-markup rules played a role in timing of the sale.

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 8, 2008.