Volume XVI, Number 14 Monday, October 12, 2009

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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 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Why Choice is Important in Healthcare

THESE ARE INTERESTING TIMES IN HEALTHCARE AND LABORATORY TESTING—both here and across the globe. In the United States, elected officials in Congress are busy assembling 1,000-page bills to make over the nation's entire healthcare system under the guise of extending coverage to those who are currently uninsured.

Overseas, the healthcare systems of other developed countries are showing cracks caused by a demand for health services that exceeds existing capacity, along with a rate of growth in health spending that is not only unsustainable, but is causing fiscal and political crises in some nations.

The American public remains oblivious to these many important stories about healthcare crises, innovations, and issues—and the analysis needed to understand them—because today's media outlets have migrated to milking the spectacular pop culture story of the moment, whether it is the death of Michael Jackson or the revelations concerning David Letterman's blackmail threats and his philandering with interns and other younger females on his staff.

For our part, THE DARK REPORT is working to fill that information vacuum by offering our clients and regular readers coverage of events outside the United States that directly touch pathology and laboratory medicine in both negative and positive ways. It is my view that pathologists and laboratory managers in this country can benefit from knowledge about how other health systems are handling laboratory testing in their own country.

Two notable examples are featured in this issue of THE DARK REPORT. On pages 3-5, you will read about the latest developments in Auckland, New Zealand, involving the troubled start-up of **Labtests**, the new monopoly lab granted an eight-year contract by the region's District Health Boards. Patients and physicians are unhappy with Labtests' service deficiencies. But because it is the only lab provider in the metropolitan area, they have no other option.

Similarly, on page 16, we provide an update to the Irish Pap smear outsourcing program. In recent weeks, flaws in the design of the government plan for cervical cancer screening have surfaced. Many physicians are publicly criticizing these deficiencies. But since it is the only major source for cervical cancer screening in Ireland, they and their patients lack the ability to choose another solution.

My message from these two stories is that "choice" is an important element in our American health system. As both patients and providers, each of us benefits from how choice fosters competition, which encourages good service! TDR

Auckland Health Boards Give DML Some Testing

Responding to problems at Labtests, officials return 10% of testing to Diagnostic Medlab

CEO SUMMARY: Auckland's chaotic lab testing situation just became more complicated. Today the Auckland District Health Boards announced a four-year contract to allow Diagnostic Medlab to perform 10% of the area's test volume, primarily for private hospitals and private specialists. Its purpose is to take some pressure off Labtests by having Diagnostic Medlab perform the more complex and sophisticated assays.

HERE'S A NEW TWIST in the lab contracting debacle involving monopoly provider **Labtests** that continues to unfold in Auckland, New Zealand.

Today the Auckland District Health Boards (DHBs) held a press conference. It was announced that **Diagnostic Medlab** (DML) would return as a contract provider of laboratory testing in the region, but in a limited role. DML was given a new four-year contract which will become effective before the end of October.

Diagnostic Medlab will provide laboratory testing services to patients being treated in private hospitals, private specialists' clinics, rest homes, and fertility clinics. This represents about 10% of the total exclusive lab testing contract that became effective between the DHBs and Labtests on September 7, 2009.

It will cost the DHBs extra to bring Diagnostic Medlab back. DML will be paid NZ$10.6 million per year. Of this amount, NZ$6.2 million will be deducted from the contract with Labtests. The additional NZ$4.4 million will be funded by the district health boards.

This is a stunning development. It is headline news in New Zealand. That's because, for the past three years, officials at the district health boards repeatedly assured both the medical community and residents of Auckland that the transition to Labtests would take place without incident or risk to patient care.

In fact, just the opposite happened. During Labtests' soft opening in August, and since the September 7 contract launch date, almost every day brought news headlines about patient wait times,

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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).

delayed lab test results, and incidents of patients getting the wrong test results. *(See TDR, September 21, 2009.)*

Thus, there is great significance in the fact that this announcement comes just 35 days after Labtests initiated service to 12,000 patients per day. By its action, the DHBs are acknowledging that Labtests failed to meet contract criteria for clinical quality and patient service. It further suggests these deficiencies are deep-seated and the time required to cure them would subject patients to unacceptable levels of risk, not to mention ongoing disruptions to the health system served by Labtests.

This is no surprise to those pathologists and laboratory professionals in New Zealand and worldwide who have followed this story since its inception in 2006. There is no precedent in modern medicine for the decision by the Auckland DHB's to grant an exclusive lab testing franchise to a company which had no laboratory and no laboratory staff in Auckland—and to have that lab company "cold start" lab testing services to 12,000 patients as of 12:01 a.m. on the first day of the new contract.

Insurmountable Task

A laboratory that size ranks in the top tier of pathology labs in Europe and North America. The sophistication of modern diagnostic testing technologies, along with highly complex IT and organizational requirements, make the goal of opening a pathology laboratory of this scale—with acceptable clinical quality and service performance—an insurmountable task. The disruptions and service problems seen in Auckland since August 10, when the first stage of Labtests' three-stage soft opening began, are evidence that Labtests failed to achieve what THE DARK REPORT characterizes as "Mission Impossible."

Newspapers and television news have widely reported the most obvious and visible breakdowns in service, such as long wait times in blood collection centers and STAT or urgent tests which did not get reported for more than 24 hours. But the most important dimension of this story, concerning patient safety, remains untold by the media in New Zealand. That is understandable, because only trained laboratory professionals understand how breakdowns in the science can cause a laboratory to imperfectly analyze a specimen and report an inaccurate or unreliable test result.

Some Problems Not Public

It is inconvenient for a patient to wait two hours for a blood draw. It is potentially life-changing or life-threatening for a patient to get a clinically inaccurate or unreliable result that might prove harmful because it leads to a wrong diagnosis or inappropriate therapy. It is this dimension of possible problems at Labtests which has not been made public.

That is understandable. If the public and Auckland physicians learned that some assays run at Labtests were producing unreliable results, chaos would ensue. Patients and physicians would demand an immediate solution to the problem. But the DHBs would not be in position to immediately fix these issues, because they put all their lab testing eggs in the single Labtests basket. That fact limits the DHBs' options to improve the current situation.

In fact, since its full start on September 7, certain facts hint at serious deficiencies in some of the lab test results produced by Labtests. For example, enough patient and physician complaints reached New Zealand's Health and Disability Commissioner Ron Paterson to cause him to go public with his concerns about the problems at Labtests. This happened on September 11, just four days after Labtests went fully operational at the 12,000 patient-per day level.

"The information I have received indicates there may be a risk to public safety given the broad concerns that have been raised," he stated. Paterson is a recognized advocate for patient safety and quality improvement in healthcare.

Paterson's comments triggered swift action by the DHBs. Only 48 hours later, on September 13, Auckland DHB Chairman Pat Snedden dispatched a team of seven senior DHB officials to Labtests. They were to oversee safety and quality functions at Labtests and the lab company would reimburse these costs.

Today's announcement by the DHBs is another clue hinting at serious deficiencies in the quality and accuracy of lab test results inside Labtests. It is a major step for the DHBs to pull the more sophisticated testing generated by the private sector away from Labtests and give it to Diagnostic Medlab—at a higher price—for four years.

DHB Quality Team Findings

Why would the DHBs take this action only 28 days after their quality team went into Labtests? Did the seven quality overseers identify serious issues affecting patient safety? Most lab professionals outside New Zealand with some knowledge of the situation believe that is likely to be the case.

The variables of simultaneously bringing up an entire laboratory full of new analyzers, demonstrating proficiency on 600+ unique assays, and turning on a newly-installed LIS (laboratory information system) are loaded with pitfalls. Add to this the challenge of hiring 400 pathologists, clinical biochemists, medical laboratory technicians, and others—then training them to newly-established protocols.

One Pacific Rim pathologist listed these challenges to THE DARK REPORT. She then speculated that it probably didn't take long for DHB quality overseers to fully comprehend the scale of the problems at Labtests. Because many of the issues affecting analytical accuracy would be systemic, months would be required to correct these serious deficiencies.

This likely also presented the DHBs with an interesting dilemma. Assume the DHBs were now informed about the ways in which patient safety would be compromised. One consequence to this knowledge is legal exposure for the DHBs if a patient sought compensation for medical malpractice after suffering a serious medical incident because of an inaccurate or false lab test result reported by Labtests.

Bringing DML Back

Finding themselves in such a situation, it would make sense that the DHBs would want to bring Diagnostic Medlab back as a contract provider. One, it demonstrates the DHBs are taking action to address the problems at Labtests. This step would generate favorable news coverage.

Two, by assigning to Diagnostic Medlab only the hospitals, specialists' clinics, rest homes, and fertility clinics in the private sector—representing the more complex reference and esoteric tests—the DHBs may be attempting to ease complaints and pressure from its most vocal critics.

Three, bringing Diagnostic Medlabs back to serve 10% of the total contract for four years gives the DHBs several useful downstream options, depending on how Labtests performs in coming months.

By no means will this be the end of the story about Labtests and the three Auckland District Health Boards. Since the controversial contract award to Labtests in 2006, these unfolding events have been followed by pathologists and laboratory professionals around the world.

More To Come In This Story

As well, it remains to be seen whether the New Zealand press will learn the details about any internal testing failures that could expose patients to misdiagnosis and unneeded or inappropriate therapy. Trust in the integrity of a laboratory test is fundamental to patient care. If it were ever to become known that actions by Labtests and the District Health Boards breached that trust, it would likely be a remarkable news exposé for both New Zealand and the world pathology community. TDR

Expert Says Time is Now For Labs to Adopt QMS

➤Growing number of reasons argue in favor of labs embracing a quality management system

➤➤CEO SUMMARY: Laboratories in the United States are knowledgeable about the use of quality control (QC) and quality assurance (QA) programs. But QC and QA represent only two small parts of a comprehensive quality management system (QMS), says Lucia Berte, an expert in lab quality. One benefit for clinical laboratories using a QMS is that it can become easier to meet the requirements of multiple regulatory bodies. Use of the QMS will also help the laboratory respond more effectively to unannounced inspections.

GROWING NUMBERS OF CLINICAL LABORATORIES in the United States are adopting quality improvement programs in an effort to boost efficiency, reduce errors, and cut costs.

In fact, adoption of such methodologies as Lean and Six Sigma by clinical laboratories and pathology groups in this country is on its way to becoming the norm. However, pathologists and lab managers should recognize that an occasional Lean project does not mean the laboratory has implemented a quality management system (QMS).

➤Quality Management Systems

Lucia Berte, MA, MT (ASCP), a lab quality consultant and founder of **Laboratories Made Better!** in Broomfield, Colorado, believes these efforts are insufficient for labs seeking to compete successfully in the 21st century. In her view, clinical laboratories should be introducing a comprehensive quality management system (QMS) such as the type described in the international medical laboratory standard known as ISO 15189. Berte believes that, once in place, a QMS would be all a lab would need when seeking to comply with any requirement from any body setting quality standards, particularly here in the United States.

"Every laboratory professional working in the United States recognizes the wide range of published requirements, laws, and accreditation standards that must be met," explained Berte. "What is problematic here in the United States is that clinical laboratories have multiple laboratory standards to meet. That is different than the situation in most other developed countries, which have a single standard for laboratory accreditation or licensing.

"In the United States, we have national agencies, such CMS, FDA, DOT, and OSHA with regulatory mandates; **The Joint Commission** with national hospital and laboratory accreditation requirements; and the AABB, CAP, and COLA with specific, detailed laboratory accreditation requirements," she noted.

"Because of these myriad requirements, laboratory managers constantly search for the 'better way,'" she observed.

"It's why there is interest in a simple, straightforward approach to quality management that encompasses and enfolds all these requirements into one integrated system. But few laboratory organizations in the United States currently have a comprehensive QMS.

More Than QC/QA

"Many labs have QC and QA, and they think that's all they need," she said. "But let's be clear—neither QC not QA is quality management! How often do we hear technologists and administrators say, 'QC/QA,' as if it were one word? At best, quality control is an operational approach that seeks to answer one question: Is this test method working right now in this batch of samples? Period. That's all you get from QC.

"Quality assurance is a little broader," Berte added. "But it asks different process questions: What is the turnaround time from sample collection to receipt in the lab and from receipt in the lab to verification of results? How many lab reports have errors in them that need correction? How many of those lab errors adversely affect the patient? Those are examples of QA questions.

"When examined closely, the standards for CLIA, The Joint Commission, and CAP are based on QA," Berte continued. "The bottom line is that these standards are not quality management systems.

Looking At Lean & Six Sigma

"In addition to QC and QA, we hear a lot about how Lean and Six Sigma projects are used to improve processes," she said. "These are methodologies. They are not comprehensive QMS models. However, that's not an indictment of Lean or Six Sigma—which are designed to support the improvement of workflow."

For pathologists and lab administrators interested in exploring the benefits of a QMS for their clinical laboratory, one starting point is the definition of a quality management system. The web site *www.businessdictionary.com* defines a QMS as:

> ***Quality Management System (QMS)***—*Collective policies, plans, practices, and the supporting infrastructure by which an organization aims to reduce and eventually eliminate non-conformance to specifications, standards, and customer expectations in the most cost effective and efficient manner.*

The widely-accepted global standard by which all other quality management systems are judged is ISO 9001. Created by the **International Standards Organization** (ISO) in 1987, it is used worldwide in all industries and by both manufacturers and service organizations, including healthcare providers.

Improvement Infrastructure

"ISO 9001 is designed to provide a quality improvement infrastructure," Berte explained. "It is a QMS model that provides the building blocks of quality improvement to allow any company or organization to apply quality principles to any work process being performed.

"ISO 9001 exists to be a generic QMS model for any company in any field," she said. "It provides the quality infrastructure while the technical requirements come from one's own industry, whether it is aerospace, electronics, food, information technology, or healthcare.

"ISO 15189 derives the ISO 9001 QMS and is tailored specifically for medical laboratories," said Berte. "Like ISO 9001, ISO 15189 incorporates QMS essentials, which include policies, processes, and procedures for every aspect of laboratory organization and operation. All the elements are addressed, such as equipment, suppliers, customers, documents and records, information management, and so on.

"Remember, a quality management system works because, everywhere you go, the building blocks of quality are the same," she added. "They are generic and universal. Further, a QMS helps a labora-

tory look at the old things in a new way. Labs have plenty of experience with QC and QA. Now the time has come for labs to elevate their thinking and incorporate a quality management system."

Based On ISO 9001

Berte, who worked on the international team responsible for developing ISO 15189, recommends that clinical laboratories in the United States consider adopting this QMS. "First, it is a system, which means a collection of approaches, ideas, and processes organized to act in a unified way. Second, it is designed to improve quality. Third, it is based on the process model of the mother of all quality management systems: ISO 9001.

"This is a one-time shift in mindset and organizational culture," noted Berte. "When the laboratory builds policies, processes, and procedures for the path of workflow to meet requirements as the work is performed, these internal standards will become integral to the culture and that lab's way of working. It is the reason why the QMS infrastructure will sustain the lab even when staff changes and when new leaders come on board."

In the United States, as of this date only three laboratory organizations have earned accreditation under ISO 15189. They are **Piedmont Medical Laboratory** of Winchester, Virginia; **Avera McKennan Health System Laboratories** in Sioux Falls, South Dakota; and **Blanchard Valley Hospital Laboratory** of Findley, Ohio. *(See TDRs, September 8, 2008, and August 31, 2009.)*

These first mover laboratories report positive outcomes from their implementation of 15189. That is important evidence that this QMS delivers worthwhile benefits to laboratories.

In Canada, ISO 15189 is gaining acceptance by provincial health authorities as the best form for laboratory accreditation. In Ontario, more than 120 laboratories are now ISO 15189 accredited. Similarly, in recent years Quebec has opted to use ISO 15189 for laboratory accreditation in that province.

ISO 15189 as the basis for laboratory accreditation is also finding favor in numerous countries across the world. In most cases, these countries have never required their medical laboratories to be licensed or accredited. Thus, when policymakers consider different options to achieve this outcome, ISO 15189 quickly surfaces as their first choice.

Raising The Competitive Bar

In North America (in Canada) and other continents around the globe, acceptance and use of ISO 15189 is likely to have two consequences in coming years. First, because growing numbers of laboratories use ISO 15189 as their quality management system of choice, this will raise the competitive bar for laboratory testing services, for a simple reason.

The longer a clinical lab operates under an effectively-implemented QMS, the more improvement in quality, productivity, and customer satisfaction it will achieve. Such continuous improvement will make the laboratory more competitive in the marketplace where it operates.

Second, as the number of countries using ISO 15189 as their basis for labora-

ISO 15189's Value to American Labs

IN THE UNITED STATES, any laboratory that wants to implement ISO 15189 will still need to separately meet all the federal, state, and local requirements for accreditation, licensure, and quality.

That's because, over the decades, the United States was one of the first developed nations to require clinical laboratories to meet accreditation and licensure requirements. As a result, the requirements of these accreditation and licensure standards were developed before ISO 9001 gained wide international acceptance as a quality management system (QMS).

Why QA and QC Are Different Than A Quality Management System (QMS)

QUALITY ASSURANCE (QA) AND QUALITY CONTROL (QC) SERVE DIFFERENT FUNCTIONS in a clinical laboratory—but neither are examples of a quality management system (QMS). Quality expert Lucia Berte of Laboratories Made Better! provided these brief definitions of QA, QC, and QMS, along with some examples or attributes of each.

Quality Control (QC)

Testing performed with samples of known values to verify that a given test method worked as intended so that patient results can be considered valid. Examples:

- Control reagents that are positive and negative—or reactive and nonreactive—for a qualitative analyte
- Control reagents with abnormally low, normal, and abnormally high quantitative values

Quality Management System (QMS)

Proactively designed management processes and procedures that build quality into the daily work processes. Includes:

- Document and record control
- Management plan for each piece of equipment
- Training in job tasks and initial competence assessment
- Ongoing competence assessment
- Complaint resolution process
- Nonconforming event reporting and analysis
- Internal auditing program
- Ongoing continual improvement

Quality Assurance (QA)

Measurements of aspects of pre-analytic, analytic, and post-analytic laboratory work processes to verify whether the process is performing as intended. Examples:

- Number of times patients do not have proper identification at time of sample collection
- Number of unacceptable samples received for testing/analysis
- Number of test orders with incomplete or incorrect information
- Number of unaccounted for ("lost") samples
- Number of times QC controls did not give the correct values and reasons for same
- Number of times laboratory instrumentation was not functional and reasons for same
- Proficiency testing performance trends
- Elapsed time from sample receipt to verified results
- Number of laboratory reports with erroneous results

tory accreditation and licensure grows in future years, that will encourage the further globalization of laboratory testing services. After all, if labs in different countries are using the same analyzers, the same assays, and the same QMS, it makes it easier to document the level of their proficiency and quality. In turn, that makes it easier for nations to outsource their lab testing to other countries based on lowest cost, while having confidence that the quality of those laboratory services is as good or better than the quality of lab services from its domestic laboratories. TDR

Contact Lucia Berte at 303-487-1135 or lmberte@LaboratoriesMadeBetter.com.

Surprise Hit with Other Participating Physicians

Scripps' Tumor Board Finds Value in Digital Imaging of Slides

➤➤ **CEO Summary:** ***When the Pathology Department at Scripps Memorial Hospital in La Jolla, California, was considering the purchase of a digital imaging system, it gained unlikely allies. Non-pathologist physicians participating in the department's tumor boards advocated for the purchase after seeing a demonstration. Pathologists at Scripps are preparing for a future in which digital imaging systems will encourage more interaction with referring physicians. These systems also could foster a move away from batch processing in pathology and toward real-time continuous flow.***

DIGITAL PATHOLOGY IMAGES ARE PROVING to be a game changer in surprising ways. That's certainly been the case at **Scripps Memorial Hospital** in La Jolla, California, where physicians participating in tumor boards advocated that the hospital spend substantial money to purchase a state-of-the-art digital slide scanner and digital pathology system because of how the clarity of the images contributed to more diagnostic precision during tumor board sessions.

"It's a rare occurrence in any major hospital for proposed spending by the pathology department to have the support of physicians in other clinical areas," observed John Spinosa, M.D., Ph.D., Chief of Staff of the Pathology Department at 293-bed **Scripps Memorial Hospital**. "In addition, since Scripps is a nonprofit health system, the purchase was to be funded with charitable grants. Typically, hospital departments argue vociferously over charitable funds. Thus, it was both unusual and significant to have plenty of backers among the other physicians at the hospital who were not pathologists."

There were the usual hurdles of convincing the health system's information technology department about the value of acquiring digital pathology scanners and a digital pathology system. But the Pathology Department found willing allies among physicians participating in the regular tumor boards. After seeing a digital slide scanner demonstration, these non-pathologists appreciated the clarity of the images and ease of use so much that they recommended the hospital spend about $225,000 to purchase the digital pathology system and fund the informatics integration.

The **Scripps Health System** in San Diego has five facilities, including four hospitals, and 26 pathologists in three pathology groups who process six million billable tests annually, almost all of them for Scripps Health patients. Spinosa's pathology group, the **Laboratory Diagnostics Medical Group** (LabDx), consists of six partners and covers two hospitals about 10 miles apart.

To evaluate how physician members of the tumor boards appreciated the new scanned images over the previous system, LabDx partners conducted a before and after survey of physician satisfaction. In the "before" evaluation, tumor board images were produced using a digital camera attached to a microscope.

The "after" survey evaluated the physicians' opinion of the images produced by the demonstration with the digital scanner manufactured by **Aperio Technologies, Inc.**, in Vista, California. Physician members of the tumor boards greatly appreciated the quality and value of scanned whole slide images over those produced with the digital camera.

According to Spinosa, acquisition of this digital slide scanner and digital pathology system is helping the pathologists deliver more value to referring physicians. It also marks another forward step in greater use of digital pathology systems by the pathologists and their colleagues at Scripps Health.

"When it comes to digital pathology images, we're using them in three applications," noted Spinosa. "The most prominent use of these enhanced digital pathology images is during meetings of the tumor boards here at Scripps Memorial Hospital.

"Second, we are now archiving selected digital images of certain cases," he continued. "Third, we plan to send out digital images of specific slides for second opinions or in response to patient requests.

"It's important to understand that, at this time, our digital slide scanning system is not used to doing sign outs," added Spinosa. "That's because the FDA has not approved these digital pathology systems for primary diagnosis."

Use of digital pathology images at Scripps Health started earlier this decade. "Using a service provided by **US LABS**, a commercial lab company, we did some remote imaging with ER/PR and HER2," stated Spinosa. "That was our initial experience with a digital imaging system.

"Although the quality of the images was not particularly good, they were fine for doing computerized morphometric measurements in immunohistochemistry," he stated. "These images had been produced by the original **ChromaVision** ACIS system. What caught our attention, however, was when US Labs began to use digital scanners manufactured by Aperio. What struck us was the immediate improvement in image quality.

Improved Image Quality

"More importantly, we recognized that pathology images of this quality would make it possible for us to make diagnoses directly from the digital image and we would no longer need microscopes," he recounted. "That was a significant revelation for us. It motivated us to evaluate the benefits of acquiring our own Aperio digital pathology system with an eye to using it for primary diagnosis at some later point.

"While using it as a primary diagnostic tool was off the table, we thought it would be a great fit for tumor boards," related Spinosa. "That might help us justify acquiring such a system. At one time, we used a video camera and a microscope to project the images for tumor boards.

"But this system had a number of disadvantages," he noted. "Next, we evolved to taking photographs, which has another set of disadvantages. We thought a digital pathology imaging system would actually offer the advantages of both systems while minimizing the disadvantages of using video and photographs."

What happened next was a pleasant surprise for the pathologists at Scripps Health. "Acquisition of our digital pathology system turned out to be a most important management lesson about the value of having support from physicians in other clinical services in the hospital," declared Spinosa.

In fact, the Scripps' pathologists followed a step-by-step process to demonstrate the value of a high-quality digital pathology image and gain institutional support for acquiring digital scanners and a digital pathology system. This successful experience offers other pathology groups with a useful road map they can follow.

"It is very important to get your physician clients involved in the decision to purchase these systems because they can be your strongest advocates," said Spinosa. "In our case, physicians outside of pathology became advocates because they recognized that these digital pathology systems help to improve patient care. The fact that our proposed new acquisition improves the care that physicians deliver to patients carries a lot more weight than anything else we as pathologists could do on our own."

However, Spinosa and his colleagues took several steps to highlight this value proposition, including before and after satisfaction surveys of physicians involved in tumor board activities. This generated objective data that reinforced the value proposition of the proposed purchase of a digital pathology system.

"To gauge interest among members of the tumor board, we asked the vendor to conduct a demonstration of the system on site," noted Spinosa. "We also conducted a questionnaire before and after each tumor board meeting. The physicians were asked 'What did you think of the slides? What did you think of the discussion?' And 'What did you think about how the Pathology Department performed during the discussion? Were you satisfied with the results?'

Pre- and Post-Assessment

"At the vendor's suggestion, we did a pre-assessment of the tumor board process using our former system, which was a digital camera attached to a microscope," Spinosa said. "That gave us a baseline of physician satisfaction with our digital photographs of pathology slides.

"Then we installed the demonstration Aperio system. The shift was remarkable and physicians at the tumor boards noticed immediately," he continued. "When we

Would Use of Digital Imaging Systems Encourage Pathology Labs to Abandon Batch Processing?

IN COMING YEARS, use of scanned digital images by pathology groups could reinforce the trend in laboratory medicine to move away from batch processing and toward continuous flow.

"The future of digital imaging systems holds significant potential," said John Spinosa, Chief of Staff of the Pathology Department at Scripps Memorial Hospital. "When you virtualize the slides, you can remove the transport.

New Opportunities

"In fact, digital images create the possibility of evaluating pathology cases in new ways that are not possible with glass slides," he continued. "You can overlay different images. Assume that, on the same slide, you had a fluorescent image and a separate H&E image. Now these two images can be overlaid.

"This is an example of how digital pathology images create new possibilities," observed Spinosa. "I think the big leap for digital pathology imaging will happen—not as a replacement for the microscope—but for doing things that can't be done with a traditional microscope.

"Use of digital pathology images will also unlock a host of changes to the entire process management of anatomic pathology," he added. "For example, most anatomic pathology is currently done with larger batch processes.

"Yet, in histology, some labs are adopting Lean techniques which involve small batch or single-piece workflow," he commented. "Another change agent is rapid processing. These approaches enable the histology lab to achieve continuous flow, often in real time.

"When your lab goes from a batch process to a continuous process, efficiency goes way up. We've seen that in the clinical laboratory.

"The natural complement to continuous processing is digital imaging of slides because it removes the need to transport the slides," explained Spinosa. "Digital imaging of slides supports a continuous flow process, and one of the last bastions of batch processing is anatomic pathology.

"There's a natural synergy there with continuous flow," Spinosa explained. "We could see that there is an expectation that biopsies and specimens would be processed continuously and come out four or five hours later—especially in an integrated network.

"If a biopsy is received at 9:00 a.m. in the pathology laboratory and is processed by 2:00 p.m., why doesn't a pathologist read it that day?" he asked. "This makes it possible to change longstanding work schedules. Now we come in the morning and leave late at night. But pathologists have to become much more like radiologists—where service hours are expanded, but the number of people on staff at any one time is smaller and there is a continuous read-out of specimens arriving in pathology.

Continuous Flow

"In this model, cases would flow continuously to the pathologists as the tissue is processed and the slides are imaged," he noted. "There is time pressure to keep patients in the hospital only as long as necessary. To the extent that knowing the pathologic condition of the patient is an important time critical factor and dropping that time is pertinent, then it becomes clear how digital imaging could bring significant improvements in patient care."

started using the digital images as opposed to the digital photographs, physician satisfaction numbers went way up!

"Clinicians immediately saw the advantages of using the digital pathology system," stated Spinosa. "These high quality images play to the strengths of pathology, because much of what pathologists do is educational. We explain our results to non-pathologists.

"That's the essence of a tumor board," added Spinosa. "And, since physicians found the educational experience so much better when we used the digital scanned image instead of pictures, it was quite easy for them to advocate strongly for using the hospital's limited grant money to purchase a digital imaging system instead of using those funds for something else.

"After the digital pathology system demonstration, it was interesting to see non-pathologist physicians advocating to get the funds for this system," he said. "As a nonprofit institution, Scripps raises money through charitable gifts. Physicians attending the tumor board said, 'We would rather use the money to purchase the digital imaging system than anything else.'

"Having these physicians advocate for this system was significant," stated Spinosa. "When it comes to use of limited charitable gifts at the hospital, it is often a bit like a food fight as every department lobbies for its interests.

"Once we decided to purchase the system, it took about a year to get all the approvals and information technology sign offs," Sinosa added. "We bought the ScanScope XT, which is a relatively high capacity system that allows us to load 106 to 120 slides at a time. Because the system went live in the fall of 2008, it's too early to determine the precise return on investment (ROI).

"But use of these digitally-scanned pathology images has definitely been worth it in one important way," observed Spinosa. "It has elevated the position of pathology in tumor boards and as a collaborator in multidisciplinary reviews. I don't know how you put a number on something that important.

"In addition, the digital pathology system gives us a window today into how pathologists will interact with their physician colleagues in future years," he continued. "After a pathologist shows the physician a digital image, the first thing a physician asks is, 'How can I see this in my office?' and 'How can I show this to a patient?'

"This is an important insight," he continued. "We all know that physicians go over radiology images with their patients. High quality digital pathology images would allow them to do similar reviews with their patients—and thereby boost the value of pathology to their practice.

"That's one advantage of digital imaging," Spinosa commented. "It improves patient care and fosters communication between pathologists and referring physicians in a way that has not been seen previously. However, for this future to become reality, we pathologists must become accessible to referring physicians and their patients in ways that we traditionally have not been.

Looking Ahead

"For now, our primary and regular use of the digital imaging system is in tumor boards," related Spinosa. "We are making preparations to expand its use for other functions.

"For example, we plan to use it to archive slides," he noted. "For second opinions and patient requests, digital images have an advantage. When glass slides are sent out, there is often no record of which specific glass slides for the case were shipped. Using digital images in these circumstances is actually a very functional utility for us.

"One hurdle to this application is that health systems currently don't want to give non-credentialed providers access to images because they don't want to violate

security regulations or federal privacy rules.

"We believe the digital pathology system has the potential for use in virtual immunohistochemistry (IHC)," postulated Spinosa. "This works because IHC is not a primary diagnosis. "Virtualizing IHC would significantly shorten turnaround because there would no transport time. We would like to do that in our next budget year, meaning possibly in 2011.

"In the meantime, our existing digital pathology system will evolve into a quality assurance (QA) resource for us," he continued. "It will allow our pathologists to look at those important or interesting cases, as well as cases we want co-reviewed.

"The pathology images can be transmitted directly to our pathologists, allowing them to accommodate the evaluations according to their workflow. A digital image can also be easily reviewed by two or more pathologists together. That is a big benefit in terms of staff efficiency," commented Spinosa.

For Spinosa, the biggest advantage will result when the FDA grants approval to use these digital pathology systems for primary diagnosis. "At Scripps, we are already using our digital pathology system in productive ways," he concluded. "Until that approval happens, we are getting a lot of utility from digital imaging. What's more, all pathologists need to get up to speed with the culture of using digital imaging systems, and we're already doing that."

THE DARK REPORT observes that Spinosa's group is getting experience with a tool that is likely to change how pathologists deliver services to referring physicians and their patients. That means, Scripps and other health systems installing digital imaging systems today will be well ahead of the curve, particularly if the FDA approved these systems for primary diagnosis. TDR

Contact John Spinosa at 858-626-6108 or spinosa.john@scrippshealth.org.

Non-Pathologists See Benefits of Digital Images

"LOOKING BACK, IT'S EASY TO SEE why non-pathologists at Scripps Health would advocate for this system," observed John Spinosa, M.D., Chief of Staff.

"When using photographs, maintaining perspective is difficult for clinicians who are not pathologists," he noted. "That's because, as the slide is moved, it blurs up and generally the field of view is much less than a digitally scanned slide. Having the physicians maintain their context is very difficult as the pathologist moves the field of view.

"Often when the magnification is switched from 2x to 4x or from 4x to 10x, it can be disorienting for non-pathologists," Spinosa said. "Changing the view will blank the screen momentarily. Then when the image returns, the non-pathologists don't quite know where they are looking compared with where they were looking previously.

"We didn't appreciate this aspect of viewing slides until we tested a fully digital system," Spinosa commented. "That context of going to a higher power where all is maintained during the dive down is really very comfortable for non-pathologists. In turn, this is a big help for physicians at tumor boards.

"Viewing digital images was not entirely new to non-pathologists, of course, because they were familiar with the ease of use with radiology images and the picture archiving and communication (PAC) system," he add. "During the demo of digital pathology images, they had an 'aha' moment when they realized pathology could have a PAC system equivalent to what radiology has. That was a strong draw for them."

Global Lab Update

Bureaucratic System in Ireland Affects Access to Pap Testing

WHEN IT COMES TO CERVICAL CANCER SCREENING IN IRELAND, health system bureaucrats have put some of the nation's women into the perfect "Catch 22."

As this happens, it provides another case study of why a government health system can often create coverage rules and restrictions which run contrary to common sense in patient care, while at the same time creating more complexities in the daily interaction between physicians and their patients.

It was just over one year ago, on July 1, 2008, when the Irish health system outsourced 100% of the nation's Pap testing to United States-based **Quest Diagnostics Incorporated**. The stated reason for this action was that it took an average of six months—and sometimes as long as one year—for Irish labs to report Pap test results to referring physicians. Under the new, multi-year contract, Quest Diagnostics pledged to report Pap tests within 10 days.

Solving The Six-Month TAT

This action was not popular with the nation's physician associations nor the pathology profession. However, on the surface, this decision by the government health system did appear to solve the ongoing problem of the six-month wait for Pap test results that was the status quo.

But now comes the Catch 22 moment. Over the past 24 months, the Irish health system has created a new national cervical cancer service called CervicalCheck. It is administered through the **National Cancer Screening Service** (NCSS).

Under its coverage guidelines, women aged 25 to 65 can get cervical cancer screening services "for free" under the CervicalCheck program. But they must first register themselves with CervicalCheck. Once registered, they will get "invitations" (appointments) for an office visit with their physician to undergo screening.

Open Access For One Year

During a one-year transition period ending September 1, 2009, CervicalCheck was an open access program. This provided time for women to register. As well, during this year, any unregistered woman between 25 and 65 visiting a physician could have a cervical cancer screen.

That stopped on September 1, 2009. Now, when a woman visits her physician, she cannot get a cervical cancer screen unless she is registered with CervicalCheck and has an invitation. In recent weeks, primary care physicians complained loudly to the Irish press that, as unregistered patients show up in the clinic wanting their regular cervical cancer screen, the physicians must turn them away because of the Irish health system's requirement for pre-registration.

And here is the Catch 22. As reported in August by the *Irish Times*, "...the letter to GPs [General Practitioners] from the CervicalCheck National Cervical Screening Programme (NCSP) states that, during the initial transition period, [unregistered] women requesting a smear test are likely to have to wait six months."

This brief overview of the ironic developments in Ireland illustrates why "Catch 22" aptly describes the situation, since arbitrary new rules mean that a woman unregistered by CervicalCheck will need to wait six months before she can get an appointment for her cervical cancer screen! TDR

GSK and Abbott Team up For Companion Diagnostic

Example of companion diagnostic strategy demonstrated by GlaxoSmithKline and Abbott

CEO SUMMARY: Although GlaxoSmithKline PLC is several years away from having a deliverable product from its Antigen Specific Cancer Immunoassay (ASCI) Program, it has a development deal with Abbott Laboratories to produce a companion diagnostic test for ASCI-based products. The interesting twist in this arrangement is that the resulting companion diagnostic assay will be designed to run on Abbott's m2000 molecular system. That would allow an expanded number of labs to run this test kit.

IN THE MARCH TOWARD PERSONALIZED MEDICINE AND COMPANION DIAGNOSTICS, a recent deal provides an early peek at how pharmaceutical companies and *in vitro diagnostic* (IVD) manufacturers are likely to collaborate to their mutual benefit.

Additionally, the reasons behind this deal provide insight about how the **Food & Drug Administration** (FDA) is considering the relevance of a companion diagnostic test as it reviews applications for new therapeutic drugs.

This summer, **GlaxoSmithKline PLC** (GSK) and **Abbott Laboratories, Inc.,** issued a press release disclosing a development deal between the two companies. Abbott Molecular will develop a PCR-based molecular diagnostic test designed to run on Abbott's *m*2000 molecular instrument platform. Both GSK and Abbott will commercialize the resulting PCR test.

This assay will be used to identify expression of the MAGE-A3 antigen in non-small cell lung cancer (NSCLC) tumors. The results of the test will be used to determine which patients are candidates to receive GSK's MAGE-A3 Antigen Specific Cancer Immunotherapy (ASCI). This is a therapeutic vaccine and is currently in clinical trials. Only patients expressing MAGE-A3 on their tumor will be eligible for this therapy and could potentially respond to treatment with GSK's MAGE-A3 ASCI vaccine.

For pathologists and clinical lab administrators, the reasons behind this collaboration to develop a companion diagnostic test are instructive. They show why pharma companies will be more actively involved in clinical diagnostics, as well as how the FDA's thinking about companion diagnostics is evolving.

Discussions With The FDA

In fact, GSK and Abbott got together because of input from the FDA. In July, *Pharmcogenomics Reporter* stated that a GSK spokesperson had told it that "It was clear from regulatory discussions that in order to launch a therapy for MAGE-A3, a regulatory approved companion diagnostic would need to be available."

Thus, once GSK understood that it would need a companion diagnostic test

to screen and qualify patients for its MAGE-A3 Antigen Specific Cancer Immunotherapy, it went looking for a suitable partner to create an effective screening test. Abbott apparently fit the bill and will develop the assay.

Indications are that GSK and Abbott will seek market approval for both the therapeutic vaccine and the companion diagnostic at the same time. Notably, this may not happen for a number of years, maybe as long as five or more years from now.

That's because GSK's MAGE-A3 ASCI vaccine is still in clinical trials. Its latest long term Phase III study of lung cancer is not projected to complete enrollment of 2,270 patients until 2011. Thus, there is no firm timetable for when market approval applications would be filed with the FDA.

The declared intention of both collaborators that the companion diagnostic test will be developed to run on the Abbott *m*2000 automated analyzer is interesting. There are two reasons why this is true.

➤FDA-Cleared Analyzer

First, because the Abbott *m*2000 already has market clearance from the FDA, there are established steps required to demonstrate the new companion assay meets specifications and produces reliable results when run on the instrument system. In turn, it is more likely that FDA reviewers would accept the data about the test's performance because it was designed to be performed on the FDA-cleared Abbott *m*2000 automated system.

Second, by selecting Abbott as its partner to develop the MAGE-A3 antigen assay, GSK can later benefit from existing Abbott customers now using the *m*2000 instrument system. It gives GSK a rapid way to build up the number of laboratories that can perform the companion diagnostic test in support of physicians treating the cancer patient.

Third—and a benefit that often goes undiscussed—by developing its companion diagnostic test on an FDA-cleared automated instrument platform, GSK can have higher confidence that the lab test result produced by the laboratory is clinically accurate, reliable, and reproducible. In other words, there should be less variability in the sensitivity and specificity performance of the test across the different labs performing the assay.

➤Analytical Variability

This is important to GlaxoSmithKline. Unacceptable rates of false positives and false negatives produced because of analytical variability among labs performing the companion diagnostic test can have significant consequences to the successful introduction, acceptance, and sustained use of the MAGE-A3 ASCI vaccine.

Every false positive means that a lung cancer patient lacking the MAGE-A3 expression would then get the vaccine—but would unlikely enjoy any identifiable therapeutic benefits. False positive patients getting this vaccine would skew the outcomes data in a detrimental manner.

In the case of a false negative, not only would the patient miss rightly being prescribed the vaccine, but GSK would lose the prescription and the revenue that comes with it. The outcomes data would also be skewed because of the false negatives.

These examples explain why pharmaceutical companies will want to be "hands on" in the way the companion diagnostic test is developed and how it is performed by different laboratories once it and the therapeutic drug have regulatory clearance to be sold in the market.

➤Companion Diagnostics

Although the companion assay to be developed by GSK and Abbott is probably a half decade or more away from market approval and clinical use, the circumstances that created this development collaboration already give pathologists and lab managers an opportunity to see one aspect of how personalized medicine and companion diagnostics are likely to evolve. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In the continuing saga of health reform efforts in Washington, DC, the clinical laboratory industry got a bit of good news, at least for the moment. In recent weeks, the Senate Finance Committee removed a provision to raise $750 million annually by enacting a tax on clinical lab revenue. The proposed tax was eliminated after lab associations complained to the committee that it was unfair. *(See TDR Sept. 21, 2009).* However, because health reform legislation is still being debated, it remains possible that other proposals to tax lab testing services could make it into the final law.

MORE ON: *Reform*

What remains in the Senate version of the bill is a provision to reduce Medicare payments to labs over five years. *USA Today* reported that Alan Mertz, President of the **American Clinical Laboratory Association** (ACLA), argued that the new provision reducing Medicare funding for lab testing would be better than the annual tax on all lab testing revenues that had been proposed earlier by the Senate Finance Committee.

CARIS ADDS 22 PATHOLOGISTS

For the second time in recent months, a national pathology company has beefed up its professional staff by hiring 20 or more pathologists. Last week, **Caris Diagnostics Inc.**, in Irving, Texas, announced that 22 subspecialist pathologists had joined the company. This brings the total number of pathologists at Caris to 61. These new pathologists represent the fields of dermatopathology, GI pathology, hematopathology, oncologic pathology/tumor profiling, and urologic pathology.

ADD TO: *Caris*

Earlier this summer, **Bostwick Laboratories** of Richmond, Virginia, announced that it was hiring at least 25 civilian pathologists from the **Armed Forces Institute of Pathology** (AFIP). *(See TDR, August 31, 2009.)* THE DARK REPORT believes that these two "pathologist hiring sprees" at Caris and Bostwick—coming just 10 weeks apart—are a sign that strong demand for pathology testing gives both companies confidence that their respective sales teams can generate enough case referrals to keep these subspecialist pathologists busy and profitable for their employers. Local pathology groups should also take these developments as portents of more competition in coming months.

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DARK DAILY UPDATE

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