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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

Pap Testing in Ireland & Massachusetts

IT IS PURELY COINCIDENTAL that, in this issue, you will read intelligence briefings about Pap testing in Ireland *(see pages 3-5)* and Massachusetts *(see pages 10-15)*. Yet, both stories, taken together, send an important message to laboratory executives and pathologists.

Because of ongoing evolution in healthcare, laboratories must continuously innovate and improve specifically to maintain their value proposition with referring physicians and payers. Ongoing change is rapidly becoming the prime directive for clinical laboratories and pathology groups. This dynamic is illustrated differently in the stories about Pap testing in Ireland and Massachusetts.

In Ireland, last year health authorities outsourced all the nation's Pap testing to a laboratory in the United States. This situation came about because Irish laboratories—for a variety of reasons—had allowed turnaround time for Pap test results to stretch out to six months, and sometimes even longer. Independent of other considerations, this created the opportunity for Irish health officials to fix this problem in a radical manner. Their solution was to outsource all the country's Pap tests to a laboratory in the United States that committed to meet a 10-day turnaround time.

I submit that, had Irish laboratories enthusiastically embraced quality management techniques—such as Lean, Six Sigma, and rapid process improvement—in recent years, they would have made great strides in slashing Pap test turnaround time. Using a proactive focus on meeting and exceeding customer expectations, Irish labs would likely have dramatically cut lengthy reporting times for Pap tests. In turn, this would have eliminated TAT as a justification by health system authorities to outsource all Irish Pap testing to an overseas lab.

By contrast, our Massachusetts Pap test story is the opposite of the Irish lab experience. At **Baystate Medical Center** in Springfield, the lab team, on its own initiative, introduced Lean methods. A first project was to reduce average turnaround time for Pap tests—specifically to better compete for outreach specimens. In a 60-day Lean project, it reduced average Pap test turnaround times by 50%.

These two laboratory management case studies make the point. In today's fast-changing world, every laboratory should think, act, and execute in a forward-looking, proactive fashion. It is smart management to protect and enhance the value proposition the laboratory delivers to physicians, patients, and payers. TDR

Bostwick Builds New Lab Around 25 Ex-AFIP Paths

Bostwick Labs' new pathology business unit intends to offer subspecialty services nationally

CEO SUMMARY: In an opportunistic business move, Bostwick Laboratories is recruiting up to 25 pathologists and a similar number of staff members from the Armed Forces Institute of Pathology (AFIP). AFIP is scheduled to close in 2011, at which time it will transition to the new Department of Defense Joint Pathology Center (JPC). Bostwick is calling its new business "American International Pathology Laboratories," (AIPL). It will operate from a new laboratory facility located in Silver Spring, Maryland.

TWO YEARS BEFORE IT IS SCHEDULED to officially close, pathologists currently working at the **Armed Forces Institute of Pathology** (AFIP) have chosen two paths to secure their futures.

Going down one path, AFIP will continue to operate as usual in preparation for its closing in 2011. As part of the Base Realignment and Closing Act (BRAC) of 2005, both the AFIP and **Walter Reed Army Medical Center** in Washington, D.C., will be transitioned and closed in 2011. However, there is an interesting future for AFIP. Pursuant to Federal legislation, plans are for the AFIP to transition to a new **Department of Defense Joint Pathology Center** in 2011.

At the same time, moving down another path, at least 25 of AFIP's pathologists are leaving AFIP as a group prior to the AFIP's BRAC disestablishment in 2011. They are joining **Bostwick Laboratories** and will create a new national competitor in the market for anatomic pathology services.

"This new pathology operation will be located in Silver Spring, Maryland, and will be known as **American International Pathology Laboratories** (AIPL). It will be a division of Bostwick Laboratories, which itself is based in Glen Allen, Virginia," stated Evan Farmer, M.D., a dermatopathologist who will serve as AIPL's director. "AIPL will offer second opinion anatomic pathology services with expertise in all organ systems.

"We are in the process of hiring 25 civilian pathologists from AFIP, along with about 25 to 30 of the civilian staff," said Farmer. "The planning for AIPL

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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).

started last spring. That is when one pathologist at AFIP contacted David G. Bostwick, M.D., our CEO and Medical Director. Collectively, these civilian pathologists have a unique combination of experience, skills, and expertise. This was an opportunity to create a unique pathology business model."

New Laboratory Facility

In recent months, the civilian pathologists were offered contracts with the new laboratory division. Meanwhile, Bostwick executives leased a lab site nearby and began work to prepare the laboratory facility.

"As these pathologists and other staff members resign from AFIP, they will begin working for AIPL," observed Farmer, who was a pathology fellow at AFIP for one year in the mid-1970s. "Not only are these pathologists experts in their fields, but they have worked together for many years. Because of ongoing sharing of cases within AFIP, these subspecialist pathologists come to AIPL as collaborators with an established history of synergy.

"AIPL wants to quickly develop relationships with pathologists and physicians who referred cases to our pathologists when they worked at AFIP," added Farmer. "We hope to have about the same case volume that was flowing to AFIP. Among the clients served by AFIP, we would like to similarly provide pathology services to such agencies as the **U.S. Department of Defense** and the **Veterans Administration** (VA). Of course, we will also be marketing to sources of civilian business."

Farmer estimated that about one third of AFIP's existing test volume comes from the Department of Defense. Another one-third originates from the VA. The remaining one-third is referred from civilian sources.

The subspecialty expertise to be offered by AIPL will be extensive. The list of services includes: breast, cardiovascular, endocrine, gastrointestinal, gynecologic, hepatic, infectious disease, neuromuscular, ophthalmic, oral and maxilofacial, orthopedic, pulmonary, and soft tissue pathology.

"It is an exciting time," commented Farmer. "These pathologists are premier experts in their fields. Our goal is to support this expertise with enhanced speed and billing capabilities to better serve clients and patients."

AIPL will launch with a national sales force already in place. "AIPL will leverage our sales force of over 140 representatives who cover territories across the United States," said Brent D. Sower, Bostwick's Vice President of Marketing. "This sales team is already marketing AIPL's services to pathologists in an effort to build the new lab's consultation business. We also want to increase our volume of primary specimens."

The Armed Forces Institute of Pathology has a long and distinguished history. Opened in 1862, during the Civil War, AFIP has a repository of 95 million tissue samples. These specimens have been accessed by medical researchers for more than 150 years. Closure of AFIP is a cost-cutting move mandated by the Department of Defense' Base Closure and Realignment Commission. In 2005, it announced plans to shut down both the Walter Reed Army Medical Center and AFIP in 2011.

Claims On The APIF Name

There was a bit of a dust-up earlier this month when Bostwick used the name AFIP Laboratories in its press release. The press release announced the opening of the new laboratory business division, along with the news that it was hiring former staff members from the Armed Forces Institute of Pathology.

As it turns out, AFIP had already pursued a trademark claim on the AFIP name. Accordingly, Bostwick adopted the AIPL name for its new business unit.

In an interview with THE DARK REPORT, U.S. Army Colonel Jo Lynne Raymond, DVM, who is the Chair, Department of Veterinary Pathology and Deputy Director at AFIP, said the institute does about 50,000

AFIP Announces: "We're Open for Business!"

"OPEN FOR BUSINESS" is the message on the home page of the web site of the Armed Forces Institute of Pathology (AFIP). It wants the world know that it is not closing now.

"The AFIP absolutely will continue to receive and process pathology consultation cases in our AFIP laboratories," says the statement on the web site. "The AFIP proudly continues to serve our beneficiaries and customers as we have done ever since our founding in 1862.

"Unfortunately, it has come to the attention of the AFIP that some contributors are confused and under the false impression that the AFIP will no longer be accepting cases for consultation after August 2009 or that the AFIP has already transitioned into another organization," AFIP continued.

"This is not the case—the AFIP has not closed. We want to assure you that the Armed Forces Institute of Pathology and its AFIP labs are still operational and located at 6825 16th Street, NW, Washington, D.C., on the campus of the Walter Reed Army Medical Center..."

The AFIP explained that the U.S. Department of Defense (DoD) is establishing the Joint Pathology Center (JPC) which will succeed the AFIP when the AFIP is "disestablished" in the Base Realignment and Closure process in September 2011. The JPC will serve as the reference center in pathology for the federal government and provide pathology services to the military healthcare system, Department of Veterans Affairs, and other federal agencies.

"There should be no decrement in pathology consultative services as the AFIP transitions to the JPC by 2011," the statement added. "So, please rest assured that the AFIP is open and definitely continues to accept military, Veterans Affairs, and civilian cases in all pathology departments and that the AFIP is committed to maintaining its tradition of pathology consultative services, education, and research.

"The AFIP and other leaders in military healthcare are committed to ensuring that DoD continues to have a one-stop shop for pathology consultation and that the transition from the AFIP to the JPC in terms of services will be transparent and seamless to our beneficiaries and customers," the statement concluded.

surgical and autopsy consultation requests per month. Currently, the staff numbers 800, of which 80 are pathologists. "AFIP is not closing and will continue to serve those who need our services," stated Raymond.

Bostwick Laboratories is making a bold move. It is incurring significant costs to hire 25 pathologists, with support staff, while building and equipping a new 30,000 square foot laboratory. All this is based on the hope that many of the clients who referred cases to these pathologists while they worked at AFIP, will want to refer cases to them at AIPL.

But then, since its founding more than a decade ago, Bostwick Laboratories has repeatedly surprised the pathology profession with its aggressive business strategies and success at generating specimen volume and revenue. In fact, its speedy and nimble grab of these 25 pathologists from AFIP is consistent with Bostwick's approach to spotting opportunities in the pathology testing market and taking quick action to exploit these opportunities.

Meanwhile, as noted in the sidebar above, leaders at AFIP are working earnestly on their plans to transition the AFIP into a new pathology service that will become operational in 2011. It will be called the Joint Pathology Center (JCP). TDR

Contact Evan Farmer, M.D., at 1-877-234-7522; Colonel Jo Lynne Raymond, DVM, at 202-782-2100.

Lab Market Update

New Lab Company Is Launched By Geisinger Health System

"Proven Diagnostics" is the name of the new firm Geisinger created to tap the lab outreach market

WITH A SIMPLE ANNOUNCEMENT last month, **Geisinger Health System** of Danville, Pennsylvania, launched a new laboratory outreach company, called **Proven Diagnostics**.

From a facility located in Bethlehem, Pennsylvania, Proven Diagnostics intends to compete for lab testing business throughout Pennsylvania. Beyond a press release issued July 21, Geisinger officials have been reluctant to say more about this new venture.

However, there are signs that Geisinger intends for Proven Diagnostics to be a formidable competitor. One hint came from the statement by Ronald Paulus, M.D., Geisinger Health System's Executive Vice President for Clinical Operations and Chief Innovation Officer. In the press release, he stated that "Our focus is on enhancing the physician and patient experience by providing easy-to-understand visual graphics, clear billing processes, specimen tracking and accountability from the time of pickup until results are reported."

Integrated Service Strategy

This specific emphasis on service execution indicates one business strategy that Geisinger hopes will differentiate Proven Diagnostics in the marketplace. In fact, earlier this year, Geisinger had purchased the laboratory informatics package called "Outreach Advantage" from **Sunquest Information Systems** of Tucson, Arizona. This informatics solution—itself developed by **PAML** of Spokane, Washington, before it sold the software to Sunquest in January this year—allows a laboratory to closely monitor and improve many aspects of service delivery to physicians' offices and other clients.

Another indication that service execution will be a primary business strategy came from Candice Miller, CEO of Proven Diagnostics. She commented that "Our Web-based connectivity solutions are designed to support physicians and their staff, and make it easy and efficient for them to interact with us."

Innovation At Geisinger Labs

For more than 20 years, the laboratory organization at Geisinger, known as **Geisinger Medical Laboratories** (GML), has been one of the nation's most progressive. It was a first-mover in multi-hospital lab and multi-site laboratory consolidation in the early 1990s. It has worked diligently to integrate both laboratory testing services and laboratory informatics throughout Geisinger Health's extensive network of hospitals and clinics.

In fact, because it is backed by the substantial resources and experience of Geisinger Medical Laboratories, Proven Diagnostics is not a typical lab start-up company. Its backing by Geisinger Health, and its ability to give referring physicians access to inpatient lab test data are likely to make it a tough new competitor. TDR

Irish Labs Appeal to Keep Pap Smear Expertise

Decision to outsource nation's Pap tests overseas makes it tough to train new doctors in cytology

CEO SUMMARY: In Ireland, pathologists are asking the government to return enough Pap tests back to the country to support and sustain medical training programs in gynecologic cytology. It was 2008 when the Irish government outsourced all Pap testing to a U.S. lab company. That forced Ireland's major cytology laboratories to shut down their cervical cancer testing, leaving them without access to the specimens needed to support medical training programs in cervical cancer screening and diagnosis.

In Ireland, laboratory professionals are taking active steps to protect expertise in gynecological cytology testing one year after the Irish government decided to outsource all the nation's Pap testing to a laboratory in the United States.

This is an unprecedented situation for developed countries. It has gone underreported and mostly unnoticed by the clinical lab testing industry in the United States. However, The Dark Report believes this is the first example of the national government in a developed country outsourcing the total caseload of a major health service to providers in another country.

For that reason, this action opens the door to what has often been discussed by pathologists: what happens when a national health service decides to outsource large volumes of clinical laboratory specimens? Will the Irish Pap test outsourcing deal become a precedent that encourages other nations to send laboratory specimens to foreign countries for such reasons as faster turnaround time, to save money, or to improve quality?

In the case of Ireland, government health officials said in 2008 that outsourcing all the nation's Pap testing was necessary to resolve excessive delays in the turnaround times for the country's Pap testing. Cost savings from the outsourcing contract were initially not disclosed to the public.

In the latest development, the **Royal College of Physicians in Ireland** (RCPI) has been negotiating with Ireland's **Department of Health** and the **National Cancer Screening Service** (NCSS) to request that some volume of Pap testing be returned to Ireland. These cases would be used in programs to train new doctors and other categories of health professionals that need these skills.

Pap Testing In Irish Labs

"We are cautiously optimistic that a solution can be reached that would see some gynecologic cytology being processed fully in Irish laboratories, which would address the training needs and also ensure that Ireland has a strategic resource and is not completely dependent on other countries to perform a critical laboratory function," stated Dr.

Conor O'Keane. He is Dean of the Faculty of Pathology at RCPI. He was quoted earlier this year in *Irish Medical News*.

Just a few weeks ago, Irish newspapers reported that government health officials were requesting that **Quest Diagnostics Incorporated**, which holds the Pap testing outsourcing contract, cooperate in subcontracting Pap smear cases back to Irish laboratories. Press accounts say Quest Diagnostics has been requested to subcontract back to Irish labs between 25,000 and 50,000 of the 300,000 Pap tests it gets annually from Ireland. Irish officials hope such a proposal can be developed by the end of September. These cytology specimens would be used for training pathologists and others in Ireland's medical school programs.

➤No Alternatives Were Offered

Within Ireland, the decision to outsource all the nation's Pap testing to Quest Diagnostics has not been without controversy. Pathologists and patient groups have pointed out that alternative approaches to solving the problems associated with gynecological testing in Ireland were not given equal consideration with the option of total outsourcing.

In 2007, the health service moved what was then called the Irish Cervical Screening Program (ICSP) into the National Cancer Screening Service (NCSS). The goal was to provide a single national cervical cancer screening program to cover the 1.1 million women in Ireland who are between 25 and 60 years of age.

This national cervical cancer screening program was launched on September 1, 2008. It is called "CervicalCheck." On July 1, 2008, just 60 days prior to that introduction, the Pap test outsourcing contract with Quest Diagnostics took effect.

A primary criticism of the then-existing Pap testing capability in Ireland was that it commonly took six months for results of a Pap test be reported. In some cases, physicians and patients might wait as long as 12 months to get the results from the Pap test. For these reasons, one primary goal of NCSS was to cut the turnaround time on Pap test reporting to 10 days. It published a public tender (request for bid) in December 2007.

➤Three Criteria To Bid

Three primary requirements in the tender were: 1) the cytology lab bidder needed to have performed a minimum of 25,000 tests during the previous year; 2) the bidding laboratory had to be accredited; and, 3) the laboratory had to be able to process a test within 10 days.

Of the six Irish laboratories which submitted bids, none were selected. In response to that news, Terry Casey, with the **Medical Laboratory Scientists Association** (MLSA), was quoted in the *Irish Times* as saying: "to send a message that none [of the Irish labs that bid] could meet the criteria to deliver this important program for the Irish public is damning."

Under criticism from many quarters about this decision, Mary Harney, Minister for Health, defended it by observing that the price submitted by Quest Diagnostics was one-third less than any bid put forth by an Irish laboratory—while also noting that Quest's services were "quality assured" and it would meet the 10-day turnaround requirement.

➤Irish Cytology Labs Closed

Now, a year into the contract, Irish laboratories which performed cervical cancer screening tests and offered specialized training in cytology have closed. The nation's medical schools have no capability to train new pathologists for the six weeks of gynecologic cytology required for them to pass their exit examinations. It is this situation which spurred pathologists to speak out. They requested that some number of cervical cancer screening tests be returned for testing in selected Irish labs to reestablish gynecologic cytology training programs.

Ireland, as the first developed nation to outsource a major and important

healthcare service such as screening tests for cervical cancer, is breaking new ground. Concerns about the inability to properly train new Irish doctors in gynecologic cytology certainly have merit.

On the other hand, the government health service has defended its outsourcing decision by pointing out that physicians and patients in Ireland now get Pap test results within a couple of weeks, and that is a major improvement from the prior waits for test results, which were commonly six months and sometimes longer.

What Comes Next?

Of course, perceptive readers of THE DARK REPORT no doubt noticed that, by the admittance of Health Minister Mary Harney, the Irish Health Service is saving 33% on all its Pap testing! That's a big win in anyone's book. And all these improvements and savings seem to have been achieved without any major problems since the outsourcing contract began last year.

What has not yet been weighed and found wanting about the "total outsourcing" strategy are the longer-term consequences to Irish patients. Will the elimination of most in-country gynecologic cytology capability prove to be an issue? It will take several more years for that question to be answered. The bad news is that, if there proves to be a problem, it will be female patients who bear the negative consequences—not the health system bureaucrats who decided to close down all the nation's operational cytology laboratories in favor of total outsourcing.

Doing Business on Low Price

There's another interesting dimension to this groundbreaking outsourcing arrangement. Might this current Pap testing contract encourage accredited and well-run laboratories from countries with significantly lower labor costs to enter bids at the expiration of this contract? Will this arrangement between Ireland and Quest Diagnostics become the door-opener that allows laboratories in countries like India, Malaysia and similar developing countries to contest for the next Irish lab test outsourcing contract?

This is why events now unfolding in Ireland may have global ramifications for pathology and laboratory medicine. Ireland's Pap test outsourcing contract may turn out to be a major step toward the further commoditization of laboratory testing. TDR

Irish Health & Quest Had Relationship Since 2006

WHEN THE IRISH NATIONAL CANCER SCREENING SERVICE (NCSS) awarded Quest Diagnostics Incorporated with a multi-year contract to perform almost all the nation's cervical cancer screening tests, it was not the first business deal between the two organizations.

As early as 2006, officials in the Irish health service were sending Pap specimens to Quest Diagnostics in order to clear backlogs of testing. These specimens originated at such laboratories as **Cork University Hospital**, The **Royal College of Surgeons in Ireland** (RCSI) in Dublin, and **St. Luke's Hospital** in Dublin. During the next two years, as many as 50,000 Irish specimens were tested by Quest Diagnostics in its laboratory facilities in the United States.

Several lab sites in the Quest Diagnostics system handled this Irish testing, including Quest labs in Irving, Texas, and Atlanta, Georgia. Public information indicates that most of the 300,000 Pap tests under the current national contract are being handled by Quest laboratories in Chicago and Teterboro.

During these two years, the contracting relationship must have gone smoothly enough for the Health Service Executive (HSE), Ireland's national health administrator, to have confidence that Quest Diagnostics was up to the challenge of handling 300,000 Pap specimens each year from Ireland under the current contract.

Lean ABN Fix Is Another $1 Million Home Run

Using Lean to Cut Pap Test TAT Pays Off At Baystate Medical

➤➤CEO Summary: ***It took only one 60-day Lean project for the laboratory at Baystate Medical Center to slash the average turnaround time for Pap tests by 50%, thereby improving its competitive position in the outreach market. Almost simultaneously, another 60-day Lean project attacked sources of write off from missing Advance Beneficiary Notices (ABNs) and incomplete insurance information—and produced an additional $1 million in collected net revenue! Both examples of Lean successes demonstrate how innovative clinical laboratories are raising the competitive bar.***

USE OF LEAN METHODS HAS UNLOCKED major improvements at **Baystate Health's Department of Pathology** in Springfield, Massachusetts. One Lean project cut average Pap test turnaround time by more than 50%. Another Lean project attacked errors with Advanced Beneficiary Notices (ABN), leading to a 75% reduction in write-offs, worth $1 million!

In the first case, the lab at this 750-bed hospital identified and corrected a myriad of small problems needed to cut Pap test turnaround time in half. As it did, it erased a significant competitive disadvantage for its lab outreach program in Western Massachusetts.

Similarly, the Lean effort involving ABN errors, by eliminating insurance verification failures at the point of care, increased revenue collections in the outreach program by almost $1 million.

"Best of all, we started these Lean process improvement efforts last fall and it took just eight weeks to produce impressive results," said Virginia Blake, M.T., Performance Improvement and Education Coordinator in Baystate's Department of Pathology. "For our lab, Lean techniques were easy to teach, easy to use, and produced remarkably fast improvements.

"In fact, the simplicity of this effort was best captured by the Lean team leader in our lab," continued Blake. "She summarized the fixes in our lab's work flow as 'It was a lot of small potatoes.' That one fact is enlightening about Lean. Removing waste in processes is not rocket science. The solutions we identified were not complicated. We fixed numerous simple and small problems—what the team leader called small potatoes—and those added up to reaching our goal.

"Lean proved effective and allowed our lab to change the system and produce these impressive outcomes within 60 days," Blake added. "We started this program in November and showcased our outcomes for the administration in January."

Characterizing the problems as many and small may be somewhat misleading given the size of the lab operation. The 21 pathologists and staff of 600 in the lab at Baystate Health perform 4.5 million billable tests annually, of which 60% are from the hospital's outreach program, known as **Baystate Reference Laboratories** (BRL). One of the top 15 largest hospital-based reference labs in the United States, BRL has 23 patient service centers throughout Western Massachusetts. The medical center itself comprises three facilities, including **Baystate Franklin Medical Center** in Greenfield and **Baystate Mary Lane hospital** in Ware, Massachusetts.

➤Identifying Projects to Pursue

"Our lab's Lean journey started about a year and a half ago with a few key projects in histology and the core lab aided by the assistance of an outside consultant with Lean expertise," recalled Jason Newmark, Administrative Director of Pathology who was hired in October. "Then, in November 2008, we brought together several key department staff (including representatives from departments other than pathology) in a conference room and identified four additional Lean process improvement projects to tackle on a priority basis.

"After identifying our four priority problems, we established a 60-day timeline to address them," he said. "This was based on our upfront assessments, including: 1) defining the problem; 2) identifying the desired outcomes; 3) determining the best way to measure progress and outcomes; and, 4) establishing an improvement schedule to achieve these goals within 60 days.

"One Lean project involved Pap smear turnaround times, two projects addressed insurance verification and Advanced Beneficiary Notices (ABN), and a fourth Lean project involved processing of inpatient CT patients in radiology," explained Newmark. "The first three projects produced remarkable results, while the radiology project stalled due to several factors, most important of which was the difficulty

providing staff dedicated time to thoroughly work through the Lean process.

"For us, the Pap test Lean project was necessary because competing laboratories in our area were reporting results in two to three days," noted Blake. "By comparison 95% of our Pap tests were reported in five to six days and our average turnaround time was four days."

"Ob-gyn doctors in the community often asked why these test reports took so long," added Newmark. "They could get Pap test results in two to three days from our primary competitors. If our competition can do it in two to three days, we needed to figure out how to do it faster.

"That became a motivator for our Lean team," he stated. "The goal was for us to equal and exceed this performance target. Not surprisingly, the initial response of several of the staff (and even the manager) in cytology was, 'There's no way we can improve the turnaround time (TAT). We're already going full out, and we're strapped.'

"Then they started the Lean process," Newmark stated. "The fascinating thing with Lean is that when you examine the processes in your lab step by step, you will see things that no one recognized were happening. This new knowledge typically overturns initial assumptions about what is, and what is not, possible to accomplish."

➤Steps Toward Improvement

Blake agreed, saying, "We identified the steps and painstakingly mapped out each one on paper. This showed where each Pap slide comes from and where it goes at every step in the process through the lab—from the time it arrived in the lab until the results were reported.

"Dissecting existing work flow in this manner allowed us to model different solutions," she explained. "We quickly identified a best case work flow scenario. A moment of enlightenment was when the team realized that with workflow changes, a Pap test could be processed and results available in 24 hours. That was an eye-opener for all of us.

"After discussing all the problems and possible solutions, the Lean team settled on adopting a system of continuous flow," Blake noted. "This was a paradigm shift for everyone, since the popular wisdom in the lab is that batching is the faster, more cost-effective way to move specimens through the laboratory. But the switch to single piece/small batch work flow was quick to implement and quick to produce results.

➤Moving Cytology Tasks

"Another source of improvement was to move some tasks in cytology over to BRL Client Services," continued Blake. "This distributed those issues to the people who could remedy them. In turn, that removed those problems from the cytology line so they wouldn't stop the flow.

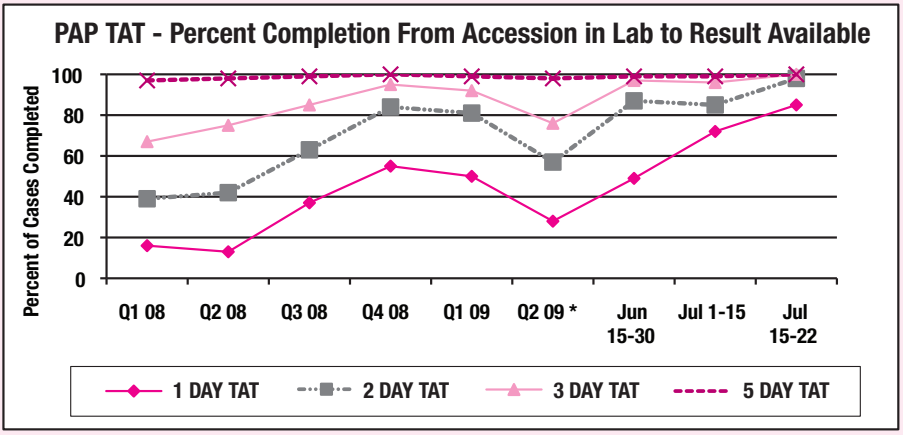
"Cross training in cytology was another change," commented Blake. "After cross-training, whenever staff has free time, they can help anytime a bottleneck develops. This gives cytology a resource it can redeploy to keep processes moving. Whether a cytotech, a secretary, or a prep tech—all can now use the same techniques to fix problems as they show up in daily work flow.

"Most impressively, these changes allowed the Lean team to reduce turnaround time—previously as long as five to six days—down to as short as 24 hours!" she declared. "Now our average is consistently two or three days, and that is 50% less time than our pre-Lean project Pap test TAT average."

"The best validation of this outcome came from outside the laboratory," recalled Newmark. "I received calls from doctors who said they noticed the improvement in TAT. That's motivating to the laboratory staff. It is great that outreach clients acknowledge the value of these improvements to their medical practice." *(See table on page 13, "PAP TAT: Percent Completion From Accession in Lab to Result Available.")*

Baystate's Laboratory Uses Lean to Drive 50% Reduction In Average Pap Test Turnaround Time in Just Eight Weeks

TO BE COMPETITIVE IN THE OUTREACH MARKET, THE LAB AT BAYSTATE MEDICAL CENTER recognized the need to reduce turnaround time (TAT) for Pap tests from its current average of five to six days. In a Lean project that lasted just 60 days, the Baystate lab streamlined workflow utilizing pull and single piece/small batch work flow. The improvements were dramatic. Before the project, 39% and 16% of Pap tests were reported in two days and one day, respectively. After the project, 98% were reported in two days (a 59% improvement) and 85% of Pap tests were reported within one day (a 69% improvement). These significant improvements in TAT were quickly recognized and acknowledged by client physicians.



Baystate Medical Center Lab's Improvement in Pap test turnaround time, Pre-Lean to Present:

Three-Day TAT: 67%, post-Lean raised to 100% Paps completed in 3 Days. 33% improvement
Two-Day TAT: 39%, post-Lean raised to 98% of Paps completed in 2 Days. 59% improvement
One-Day TAT: 16%, post-Lean raised to 85% of Paps completed in 1 Day. 69% improvement

Unlike the Pap smear test initiative, Baystate Lab's other successful Lean project had an internal focus. It targeted write-offs involving ABNs and insurance claim rejections.

Newmark set the scene. "Last fall, we determined that our lab was writing off about $1.5 million per year in net income due to insurance verification information that was wrong or because of ABN errors," he explained. "About 60% of this total ($900,000) involved ABN errors. The balance of these write-offs, $600,000, were due to failures to verify insurance coverage.

"These problems occurred because we didn't have the right systems in place and we didn't have the right data for tracking," he continued. "Moreover, we had not done a very good job educating our referring providers about how to manage ABNs or educating our patients on what an ABN was and what it meant to them financially. Further, in comparison to overall gross revenue, the write-off amount due to insurance and ABN issues represented less than a 0.5% write-off rate. That is one reason why the issue of lost revenue unfortunately fell off the radar screen.

"Yet, this is money legitimately owed to our laboratory," Newmark added. "What prevents us from collecting those funds is our failure to collect the right data at the right time and educate our patients and providers. The goal of this Lean project is to identify these failure points and implement effective processes.

Insurance Verification

"In mapping the processes involved, we determined that there were only a few ways that patients come to us," said Newmark. "For example, patients can show up at our patient service centers (PSCs). Another other way is when they visit doctors' offices, where the specimens are collected and transported to our lab by couriers. A third way is that specimens are collected from inpatients here in the hospital.

"Oddly enough, prior to starting this Lean project, everyone believed that doctor's officers generated the largest number of problems with ABNs and insurance claims," stated Newmark continued. "But as we mapped our processes and identified the sources of errors, we were surprised to find that the vast majority of these problems originated with patients who visited our own service centers!

"This was a positive finding, because we have more control over the procedures that take place in our patient service centers," he added. "On the other hand, it was disappointing to learn that, under the existing work flow, staff in the PSCs lacked sufficient procedures and tools to verify insurance coverage or to ensure Medicare patients signed an Advance Beneficiary Notice.

Working With ABN Forms

"As most lab managers know, the ABN, sometimes called a waiver of liability, is the form medical providers give to patients when they believe Medicare may deny coverage," offered Newmark. "If Medicare denies coverage for the service, the patient would be responsible to pay for the service or appeal the denial. In either case, an ABN is needed if the provider wants to bill the patient.

"Value stream mapping of work flow showed us how specimens from the PSC were arriving in the accessioning area with flawed paperwork," he said. "At that point, it is too late to ask the patient for insurance information or ask them to sign an ABN. Consequently, our staff must spend time contacting the patient or the doctor's office in an effort to acquire the needed insurance information necessary to submit a complete, clean claim. Not only is this disruptive to patients and providers, it is waste (Muda) for staff to chase after information that is best gathered upfront, at the time the patient's specimen is collected.

"Having identified the primary sources of these ABN and insurance billing write offs, our Lean team took steps to implement improvements to the process," Newmark stated. "To address problems that originated with specimens submitted from doctors' offices, we contacted our physicians' offices directly and, where possible, arranged meetings with the physicians and their staff.

Receptive Physicians

"It was a pleasant surprise to find the physicians very receptive to helping us," he continued. "Our approach was to explain the problem to them and ask for their suggestions on how to address it. In almost all cases, they asked us to do two things.

"First, we were asked to educate the providers and their staff members about revising requisitions to clearly denote tests that would require ABNs and provide the list of common tests that require ABNs," said Newmark. "Second, we were asked to provide or recommend software and online tools they could use to verify insurance coverage. We also asked the doctors to have their patients sign the ABNs in their offices rather than wait for our lab staff to call the office asking for additional information. Many offices did agree to manage ABNs in their office, a step in the right direction!

"The Lean team took other improvement steps," he added. "Revenue management workflow was reorganized so that ABNs could be run on all send-in specimens, including follow up contact with the client on specimens that fail medical necessity. These improvements further reduced write offs.

"Simply put, in just over nine months, our Lean improvements have increased cash collections by almost $1 million!"

"Next, the Lean team turned its attention to the staff at the patient service centers," recalled Newmark. "Everyone working in the PSCs was made aware of the problem and the implications associated with losing $1.5 million because of the write-offs. This was key. We communicated with our staff and asked them to be part of the solution.

"PSC staff was concerned that taking time to verify insurance coverage or get patients to sign ABNs would slow everything down," he said. "The Lean team responded by installing software tools in each PSC that handle eligibility verification and include an ABN checker.

Working With PSC Staff

"The next step was to educate the PSC staff and everyone involved in how to verify insurance and how to handle ABNs" added Newmark. "This job is made easier by the fact that Medicare requires an ABN for only about 55 tests.

"Another change to our work flow is that we now have all patients give us the information and sign the forms up front," explained Newmark. "Since October, these work flow improvements have reduced the amount of write-offs by about 75%. Simply put, in just over nine months, our Lean improvements have increased cash collections by almost $1 million!

"This is an interesting problem for the clinical laboratory because where I worked previously (in radiology), patients wouldn't be served until it was known that the patient's registration information was accurate and, where necessary, an insurance pre-authorization was on-file (if required), especially for a CT or MRI scan," observed Newmark. "Plus, in radiology, patients are scheduled, which allows time to verify insurance information and collect authorizations. In the lab, many patients are not scheduled. They simply show up at the PSC, which makes validating information ahead of time nearly impossible. However, with changes to our workflow, we now have systems in place to verify insurance coverage or ensure that the ABNs are signed. That is making a big difference."

New Lean Projects

Motivated by the successes of the Lean projects involving Pap testing and write offs associated with insurance claims and ABNs, Baystate's Lean team is pushing forward with new projects. "Currently the Lean effort is tackling work processes in transfusion medicine, as well as results reporting and workflow in anatomic pathology," noted Newmark.

It is most common for laboratories that adopt Lean to apply it first in such areas as accessioning and the high-volume chemistry and hematology lab. So it is noteworthy that Baystate pursued different objectives with its initial Lean projects.

With the project to cut average turnaround times for Pap test reporting, the laboratory improved its competitive position in the outreach marketplace. The Lean project to reduce write offs due to incomplete insurance information or missing ABNs clearly demonstrates the power of Lean. In an eight-week Lean project, Baystate picked up an additional $1 million per year in collected revenue. TDR

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Third Laboratory Earns ISO 15189 Accreditation

Empowered lab staff, continuous improvement are two benefits for Blanchard Valley Hospital lab

CEO SUMMARY: In June, the laboratory at Blanchard Valley Hospital became third in the nation to be accredited to ISO 15189:2007. The 150-bed acute facility in Findlay, Ohio, is the only hospital laboratory of its size to achieve accreditation to the ISO 15189 standard. Implementing these standards directly benefited the lab by lifting what was already a top-performing organization to a higher level of achievement. The ISO standards also support an effective culture of continuous improvement that challenges the lab to repeatedly raise the bar.

LAST JUNE, THE LABORATORY at 150-bed **Blanchard Valley Hospital** (BVH) in Findlay, Ohio, became the third lab in the nation to be accredited to ISO 15189:2007.

The lab is using its new ISO accreditation to further expand its laboratory outreach program. "We intend to market the outreach program as one that meets and exceeds higher standards of quality than any other lab in Northwest Ohio," said Bonnie Van Schoik, MT (ASCP), Administrative Director of the Blanchard Valley Hospital Laboratory. The laboratory was already CLIA certified, accredited by the **American Association of Blood Banks** (AABB), the **College of American Pathologists** (CAP), and **The Joint Commission**. It used the program offered by the CAP to achieve its ISO 15189 accreditation.

To date, the key benefit from the ISO 15189 experience has been to ratchet up an already top-performing laboratory to a higher level of operational excellence. "The process began in December 2007, when CAP invited us to be a part of the pilot program for ISO 15189 accreditation," Van Schoik said.

"The ISO process enabled our staff to learn a great deal about ourselves, our processes, and the quality of our laboratory," she commented. "It was productive to dissect our procedures and determine how we could improve our laboratory operations. The journey to becoming ISO 15189 compliant has been great for team-building. It taught us how be effective change agents; the Blanchard Valley Hospital Laboratory is an outstanding quality laboratory because of this process."

Lessons Learned

During an interview with THE DARK REPORT, members of the lab staff identified four significant lessons for other laboratories considering ISO 15189 accreditation. First, the lab found it needed the full support of both hospital administration and laboratory staff. Second, it recognized how software was an effective way to support documentation. Third, it learned the value of empowering staff to serve as problem solvers and change agents; and fourth, the

lab eliminated a surprising number of process inefficiencies.

"Our hospital administration was supportive of this project to become ISO 15189 compliant," noted Van Schoik. "That included an investment of $25,000 in software to support documentation, along with an annual investment of $9,000 to maintain the software and provide upgrades as needed."

"The upfront buy-in of both hospital administration and laboratory management is essential," noted Lisa Selhorst, MT (AMT), Regulatory Compliance Quality Manager. "That's because it takes significant resources, including staff as well as financial support, to implement ISO 15189."

No Outside Consultants

The BVH laboratory opted to not hire outside consultants, but to pursue its ISO 15189 accreditation as a "do it yourself" project. "Labs that do this work on their own—as we did— are likely to learn more about the ISO standards," stated Selhorst. "We think that it makes it easier for laboratory staff to become more engaged in the process, since an outside consultant is not dictating what needs to be done. We found our staff would embrace changes more easily when they were directly involved in process improvements."

One major benefit to adoption of ISO standards is how it unlocks further productivity gains in the laboratory. "As laboratory staff identifies ways to improve individual processes, the results are often remarkable," observed Doug Hughes, MT (ASCP), Laboratory Information Systems Coordinator. "That's true for two reasons.

"First, ISO standards require our lab staff to break down, analyze, and improve what is done in the laboratory in a way that we had never done before," he explained. "Second, this review and improvement process will be continuous as long as our laboratory is involved with ISO accreditation.

"This is a notable difference—and a major benefit to ISO 15189," added Hughes. "With other accrediting standards, once the lab meets the standards, it is finished. The great thing about ISO 15189 is that your lab continually improves.

"Probably the most useful tool we used in achieving accreditation was a document management control system," said Hughes. "This is a tertiary piece of software that we run on our **Meditech** System.

"Because ISO 15189 requires documentation of every step in every process, document management is a significant part of the undertaking," he stated. "This software guided us through the process. We were constantly surprised by its ability to identify what we needed to do at each step. More importantly, our use of this

ISO 15189 Standards Drive Continuous Improvement

WHAT MAKES ISO 15189:2007 different from other laboratory accreditations is that it goes beyond a checklist. Thus, implementing ISO standards means ongoing effort.

"Generally, these standards are not prescriptive, meaning they don't tell you how to do it," said Lisa Selhorst MT (AMT), the lab's Regulatory Compliance Quality Manager. "Rather, the standards describe what needs to be accomplished.

"Initially, our staff found working with these standards, to be a bit frustrating," she added. "However, the genius of this approach is it allows you to mold each ISO standard to your laboratory's unique needs, in ways that are a direct benefit."

"Another advantage of ISO 15189 standards," offered Bonnie Van Schoik, MT (ASCP), the lab's Administrative Director, "is that our laboratory must regularly look at a standard and compare it to current practice. This approach results in ongoing and continual improvement to processes in the laboratory."

document control system helped us save time and money."

In fact, putting all documents in a single document management system has itself unlocked major cost savings and helped improve productivity. "Before implementation of the document control system software, we had more than 85 policy and procedure manuals on paper in binders," observed Van Schoik. "Now every policy is available via the search function on each computer. This new system saves an enormous amount of time."

Empowering Staff

"One significant benefit of ISO 15189 is how it has empowered laboratory staff to continously improve laboratory processes," commented Selhorst. "In turn, this contributes to greater productivity, fewer errors, and reduced costs. It also motivates our staff; they can see direct progress resulting from their efforts.

"It means each staff member must be vigilant about identifying deficiencies," she continued. "One direct advantage of achieving accreditation is increased ownership of all laboratory processes. In a fundamental way, everyone who works in the lab now has a voice for improving any process. We also implemented problem logs, which increased everyone's awareness about the issues we need to address.

"Empowering the entire staff is an important achievement, because now the staff realizes that we listen and take action to improve processes that affect them," noted Selhorst. "Both lab staff and lab management want to know: what processes are working and what's not working throughout the entire laboratory? This active role by our staff in day to day operations has made a powerful and positive difference for our laboratory."

"One visible aspect of this staff involvement was in the documentation process," stated Laboratory Manager Jeanette Theis, MT (ASCP). "Everyone was involved in procedure writing... the med techs, the staff, and phlebotomists as well! Each policy or procedure throughout the entire laboratory needed to be either written or updated into the electronic document control system. Teams of associates from all shifts and job classifications conducted root cause analysis to help improve processes."

Recognizing the effort required by lab staff to meet the ISO accreditation requirements, certain fun elements were introduced. "For example, we gave prizes for what we called 'ISO-tizing," explained Theis. "That's a term we made up to describe when someone made a suggestion to help 'ISO-tize' our lab by fixing ISO nonconformities.

"For each contribution, the staff member could get an 'I,' 'S,' or 'O.' Once an individual got a full ISO, he/she earned a prize, along with a chance to win a week-long paid vacation. This was a way to add some fun to the project and reward staff."

THE DARK REPORT observes that perhaps the most powerful result from the initiative is the staff has taken quality to a level no one believed was possible. Van Schoik agreed, stating, "Certainly we were a quality lab before we began our journey to become ISO 15189 compliant. But our adoption of ISO standards has been an impetus to push our quality performance to even higher levels.

Recognized By Community

"This achievement has given us positive exposure," Van Schoik commented. "Business and industry recognizes that ISO is a quality marker. Members of our community can be assured that, as an ISO 15189 compliant laboratory, we are here for them, and want to exceed their expectations as their laboratory service provider. Compliance to the ISO 15189 standard sends a powerful message about our commitment to provide high quality laboratory testing for our patients." TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

These days, you hear plenty about Web 2.0 and how it is revolutionizing the way people use the Internet. Pathologist Keith Kaplan, M.D., at the **Mayo Clinic** uses the term "Pathology 2.0" to describe how use of Web 2.0 technology will similarly transform the anatomic pathology profession. Now comes interesting evidence that Pathology 2.0 is advancing as a trend. On August 24, the **American Association of Bioanalysts** (AAB) issued a press release touting its new digital proficiency testing (PT) service for whole-slide digital imaging. AAB offers images for PT that can be accessed through a standard web browser, using a free plug-in.

MORE ON: Path 2.0

AAB says that its whole-slide digital image PT allows the pathologist "to view a slide on a computer as you would view it on a microscope—zoom to any magnification up to oil immersion, adjust color, contrast, and move in any direction. You can use the micrometer to measure any object in the field of view." By its introduction of a whole-slide digital imaging PT service, AAB is indicating that it believes adoption of digital imaging in anatomic pathology has advanced enough to make this proficiency testing service viable.

APERIO EARNS ISO 13485 CERTIFICATION

Staying on the subject of digital imaging, last week **Aperio Technologies, Inc.**, of Vista, California, announced its certifcation as compliant with ISO 13485:2003. This involves "the design, manufacture, distribution, and servicing of digital image analysis systems and digital scanning services." It used **BSI Group** as its registrar. BSI is a global player in ISO registrar and consulting services.

QUEBEC REVIEWING BREAST BIOPSIES

This spring, health system authorities determined that some laboratories in Quebec may have reported inaccurate results for breast cancer tests. Initially it was announced that breast cancer tests for 2,100 women would be independently reviewed for accuracy. Then, last month, the health minister announced that another 630 breast cancer tests would be added to the independent review. Laboratories in provinces outside of Quebec are handling these case reviews. It is anticipated that their findings will be released before the end of the year.

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...

...efforts by **Neogenomics, Inc.**, to develop a FISH-Based assay for diagnosis of melonoma, using proprietary probes licensed from **Abbott Laboratories**. Target for market introduction is 2010.

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 21, 2009.

Now in its third year!

PREVIEW #4

Lab Quality Confab

on Quality Management in Diagnostic Medicine

September 29-30, 2009 • Hilton Hotel• Atlanta Georgia

Ralph Dadoun of St. Mary's Hospital Center on:

Blending Lab Automation and Lean: Best Practices in Pairing These Powerful Tools

At 316-bed St. Mary's Hospital, the lab applied both Lean and lab automation to improve performance. Learn the "best practices" identified by this lab as it studied the successes of other labs and applied them to its internal work flow. With 3.1 million tests per year and an active lab outreach program, the St. Mary's lab demonstrates the power of blending Lean and lab automation in effective ways. It has also earned accreditation under ISO 15189.

For program details and to register:
visit www.labqualityconfab.com

UPCOMING...

- ***Payers Finally Want Enriched Lab Test Data: How Your Lab Can Leverage Data for Network Provider Status on Favorable Terms.***
- ***Report from the European Congress of Pathology: What's New. What's Hot. What's Not!***
- ***How Direct-to-Consumer Advertising Builds Consumer Demand for Predictive Genetic Testing***

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