Volume VIII, Number 14 Monday, October 15, 2001

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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R Lewis Dark

Founder & Publisher

Biological Warfare Threat Takes Center Stage

NEWS THAT ANTHRAX SURFACED IN NEW YORK CITY AND WASHINGTON, DC comes just as we send this issue to the printer. It follows by days the discovery of anthrax in Florida. Not surprisingly, the fear of attacks by biological and chemical weapons is taking center stage in the United States. It now dominates media coverage of the war on terror.

Clearly such events place clinical laboratories and anatomic pathology squarely in the line of fire. Responding to biological and chemical attacks requires lots of help from laboratories. In many cases, as people show up in emergency rooms, it will be the hospital labs which get the first specimens, along with the job of identifying whatever active agent has affected the patient. But that's not to say that commercial labs, receiving specimens from physicians' offices, may not also be first to identify patients who've been exposed to biological or chemical attacks.

The evidence that anthrax was deliberately sent to separate locations in two states will have a chilling effect on our society. Even as Miami officials were beginning to test postal workers for anthrax, the Miami local of the **American Postal Workers Union** (representing clerks and distribution workers, not mail carriers) sent a letter to the White House with a demand for safety measures and training. Imagine what would happen if workers in the post office and overnight delivery companies refuse to handle mail and packages without onerous safety precautions.

These are new threats to our society, and it is the nation's system of laboratories which will become one of the "canaries in the coal mine." Laboratories will be among the those healthcare providers who would be first to see and recognize patients affected by biological and chemical weapons, notifying government officials of such occurrences.

Within our industry, I predict we are undergoing an earthquake of significant proportions. As events related to the newly-declared war on terrorism shake our country, laboratories will be required to develop a whole new level of management procedures and crisis contingency plans. It will require significant investments in management time and staff training to bring this about. There is something which makes this particularly different and more than a little scary: any attacks with biological and chemical weapons directed at the public may also threaten those laboratorians who must come in contact with the victims of these attacks and their specimens. TDR

Nation's Anthrax Cases Bring Bioterror to Labs

Number of cases mushrooming daily as evidence points to terrorist activity

CEO SUMMARY: America's clinical laboratories are soon to be enlisted in the war against terrorism. Concerns about chemical and biologicial terrorist attacks have reached high levels following the death of a Florida man from pulmonary anthrax and the discovery of letters containing anthrax mailed to Tom Brokaw of NBC News and Senator Tom Daschle of North Dakota. Authorities are working to link these events to terrorists.

THE DEATH OF ONE MAN from anthrax in Florida and the discovery of a growing number people either infected or exposed to anthrax triggered a media frenzy over the spector of terrorist attacks using biological agents.

As THE DARK REPORT goes to press today, at least 12 people, primarily in New York and Florida, have tested positive for anthrax. Government investigators are treating all episodes as crimes and believe the anthrax was intentionally introduced.

Regardless of what this investigation concludes, heightened media attention on the subject of chemical and biological terror in the United States is forcing government authorities to take serious steps to prepare for such attacks. As they do, clinical laboratories throughout the country will become involved and begin developing plans for how their organization will detect these types of attacks and what they will do in response to them.

Already, long-standing efforts to formally organize a response plan among selected regional laboratories are accelerating. Increased funding from Congress to support such preparations in hospitals is a given. The only question is how much money will be earmarked to support this program.

The thought of biochemical attacks is horrifying to most Americans. Indeed, many in the media and some in the government have painted gruesome pictures of how such attacks could wreak mayhem upon the population.

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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., 1731 Woodland Terrace Center, Lake Oswego, Oregon 97034, Voice 1.800.560.6363, Fax 503.699.0969. **(ISSN 1097-2919.)**

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.55 per week elsewhere (billed semi-annually).

However, most laboratorians understand enough about the dynamics of disease and diagnosis to know that the existing system may already be positioned to do a better job of detection and response than the public perceives.

Pulmonary Anthrax Victim

Case in point is the death of Bob Stevens on October 5, the unlucky victim of pulmonary anthrax. Stevens was brought to **JFK Medical Center** in Miami mid-week, showing a variety of symptoms.

Although authorities have not publicly disclosed specific details of how the disease was diagnosed, laboratorians with connections to JFK Medical Center tell THE DARK REPORT that the story circulating there is this: the attending physician, after viewing the chest x-rays, knew the disease was not pneumonia and referred the x-rays and case work-up to the **Florida Department of Health**. The Department of Health made the diagnosis of pulmonary anthrax and referred the case to the **Center for Disease Control** (CDC) in Atlanta, which confirmed the diagnosis.

This all happened within a day or two of the patient's admission. It was the first case of pulmonary anthrax in the United States since 1972 and only the eighteenth reported case in the country since 1900.

Fast, Accurate Diagnosis

Certainly it is a fact that the medical establishment is now paying attention to the potential for biochemical attacks since the events of September 11. But the rapid identification of a seldom-seen disease by JFK Medical Center's physicians in the Bob Stevens case is reassuring. THE DARK REPORT believes it is representative of how emergency room physicians and their supporting laboratories throughout the country utilize the reference and esoteric testing resources to rapidly identify unfamiliar or unusual diseases.

For the clinical laboratory profession, a variety of changes will be implemented by government authorities and legislators. In Congress, Senators Edward Kennedy (D-Mass.) and Bill Frist (R-Tenn.) introduced legislation calling for an increase of $1.4 billion in spending to prepare for biological and chemical attacks. At least $295 million would be directed toward "improving hospital response capabilities."

The federal **Center for Disease Control and Prevention** (CDCP) are helping state and local health departments acquire and deploy automated equipment that will run molecular tests for antibodies and DNA probes. The goal is to perform more sensitive and accurate testing as fast as possible, and do it closer to the site of possible biological or chemical incidents. Currently it takes two or three days to confirm a diagnosis. The goal is to cut that down to hours.

Tighter Controls On Labs

Another change on the way is tighter controls over infectious agents in clinical and research labs. For example, it is estimated that at least 5,000 labs in the United States hold quantities of 42 agents listed by the CDCP as dangerous pathogens. Upwards of 150,000 labs in the United States hold small amounts of microbes for "reference cultures." These are used to aid in identifying suspected pathogens following an outbreak or environmental release.

These examples demonstrate that elected officials and government regulators have begun to pay closer attention to the way laboratories operate, and their role in the early and accurate detection of biochemical attacks. Expect more changes in the months ahead. **TDR**

Contact Robert Michel at 503-699-0616.

Biological Warfare Has Important Limits That Make It Most Difficult to Employ

ONE EXPERT BELIEVES BIOLOGICAL WARFARE is not the ready weapon of mass destruction that many perceive it to be.

"It's important to remember that guerilla warfare and terrorist action operates from three principles," said Henry I. Miller, M.D., Fellow at the **Hoover Institution at Stanford University** and an offical at the **Food and Drug Administration** between 1979 and 1994.

"Successful operations must be: 1) simple to execute; 2) offer the terrorists a high degree of security before and during the attack; and 3) provide surprise to those attacked," he explained. "Biological warfare is a complex undertaking, and fails on at least the first two of these principals. It is not a trivial undertaking to grow and weaponize biological agents."

In an exclusive interview with THE DARK REPORT, Dr. Miller emphasized an overlooked fact that would affect biological warfare. "Over the past half-century, university and government research labs working with infectious agents have, unintentionally, performed what amounts to small-scale biological warfare 'experiments'," he said. "In other words, there were laboratory accidents in which organisms were released.

"The outcomes of these incidents are revealing and somewhat reassuring," continued Dr. Miller. "The U.S. Center for Disease Control in Atlanta, which used to monitor these mishaps, recorded 109 laboratory-associated infections during the period 1948-1973, but not a single secondary case—that is, of a patient's family member or community contact—was reported."

Dr. Miller says a review of medical literature will show a similiar pattern of limited secondary infections involving exposure to infectious diseases. His conclusion? "Although a future lethal epidemic caused by progressive person-to-person spread of infectious agents is unlikely, their widespread dispersion—throughout a subway system or in the ventilating system of an office building, for example—potentially could infect thousands of people," he noted.

Dr. Miller observed that diseases, to spread throughout a population, need an efficient vector. "Bubonic plague killed on a wide scale in the Middle Ages because the vector, fleas, went unrecognized. Also, the incubation period for most diseases requires days, creating an opportunity for medical intervention.

"In theory, I believe smallpox has the most destructive potential," he continued. "But it is a challenging and complex process to grow smallpox and convert it into a weapon. Also, there is residual immunity among those previously vaccinated."

Dr. Miller advocates a reasoned approach to biological warfare. He believes that the existing medical system in the United States has a great capacity to detect and identify disease. "Think about what happens when an international traveler becomes sick in the United States," he said. "Whether it is West Nile Fever or some other disease not often seen in this country, an accurate diagnosis is made rather quickly."

Because of this existing capability, Dr. Miller says "the prospect of exposure to biological weapons should elicit not hysteria, but vigilence and planning. Louis Pasteur, the father or bacteriology, was correct that 'chance favors only the prepared mind'."

Lab Industry Briefs

LAB MEETINGS CONTINUE WITH STRONG ATTENDANCE

DESPITE THE HASSLES that now come with cross-country travel, laboratorians throughout the United States continue to support industry meetings.

Traditionally the largest lab meeting of the fall season, "Lab Institute 2001" expects good attendance. Dennis Weissman, Publisher of *Washington G-2 Intelligence Reports* and producer of the conference, tells THE DARK REPORT that a sizeable crowd will be on hand when the meeting convenes in Washington, DC on October 26.

"If anything, recent events have made it even more important to get good information and stay on top of what's changing," noted Weissman. "Registrations are flowing in steadily and we believe this is the reason."

Another lab association producing a full slate of meetings is the **American Association of Clinical Chemistry** (AACC). Following its lab automation meeting earlier this month, it has meetings scheduled on molecular diagnostics (San Diego–Nov. 8-10) and laboratory reimbursement (Washington, DC–Nov. 15).

"In the aftermath of recent events, registrations for our meetings have declined somewhat, by about 25%," stated Jerry Goldsmith, AACC's Vice President of Marketing Programs, "However, we've maintained our normal schedule of meetings and are adding a meeting on biological and chemical terrorism for December."

CERNER AND IBM ANNOUNCE PARTNERSHIP

LOST IN THE EVENTS OF SEPTEMBER 11 was the news that **Cerner Corporation** and **IBM** had entered into a global strategic alliance.

The companies announced that the alliance is to "wrap IBM's worldwide e-business technology, marketing, and sales capabilities around Cerner Millennium™, the company's clinical, management, and knowledge software application systems."

Effectively, the goal is for both companies to sell each other's products. Cerner will promote IBM's computers, servers, storage area networks, and middleware. IBM will market Cerner's Millennium.

IBM, **Motorola, Intel** and other big players in computers and informatics have their eye on the healthcare marketplace. The Cerner-IBM alliance is representative of a number of similar partnerships designed to position these corporations for a bigger share of the market for healthcare informatics.

GENE-BASED DNA TESTING DEAL ANNOUNCED

WALL STREET HAS LONG BEEN INTRIGUED by **Visible Genetics, Inc.**, a Canadian company developing technologies to allow the high-speed sequencing of genes linked to disease.

On September 28, Visible Genetics received market clearance from the FDA for its TRUGENE™ HIV-1 Genotyping Kit and OpenGene™ DNA Sequencing System. Just days earlier, Visible Genetics announced that it had entered an agreement to allow **Bio-Reference Laboratories, Inc.** of Elmwood Park, New Jersey to market the tests in the New York, New Jersey, and Philadelphia areas.

Besides its physicians' office testing business, Bio-Reference does a sizeable volume of prison and jail testing. It is estimated that up to 35% of all prisoners are HIV-positive. TDR

NYC Lab Hand-Entered Reqs After Terrorist Acts

Electronic test ordering/reporting link severed by attack on World Trade Center

CEO SUMMARY: Crisis management was the watchword at Centralized Laboratory Services, Inc. of New York City following the terrorist attacks on September 11. Damage around the World Trade Center knocked out the communications link between the lab and a data server which transmitted electronic test orders and results. The lab found itself forced to hand-enter thousands of paper test reqs per day to maintain test services.

IMAGINE, ON AN EMERGENCY BASIS, hand-entering 7,000 paper requisitions into the LIS every day! That's what happened on September 11 to **Centralized Laboratory Services, Inc.** (CLS) of New York.

Despite its location in Queens, a safe distance from the havoc wrought by terrorist attacks in Lower Manhattan, Centralized Laboratory Services, Inc. found itself facing a unique crisis on that fateful Tuesday.

"The data server which feeds us electronic test orders and transmits our test results is located in Lower Manhattan, not far from where the World Trade Center stood," stated Eugene S. Pearlman, M.D., Medical Director at CLS.

Link To Data Server Lost

"The telephone lines which connect us to our data server ran through the telecommunications hub which was destroyed by the collapse of the twin towers," he said. "The destruction of this facility meant our lab could neither electronically receive test orders nor electronically report test results. Because our entire testing work flow is organized around the computer server, losing this data link crippled our lab."

That's because CLS is organized in a unique way, different from just about every other clinical laboratory in the United States. CLS is a division of **Health Insurance Plan of New York** (known as HIP). HIP is an HMO which serves 1 million people, primarily government employees, police, and fire fighters.

"There are 47 HIP medical centers around greater New York," he continued. "Test requests are electronically transmitted to HIP's headquarters and data center, where eligibility is checked. The data center then forwards those test requests to CLS. When the test results are available, CLS transmits them through the data server to the referring physician.

"Our entire work flow is organized around the electronic transmission of test requests from the physicians to the lab and test results from the lab back to

the physician," explained Dr. Pearlman. "That is why the loss of telecommunications was so crippling to our lab."

Hand Entry of Test Reqs

Daily, CLS handles about 7,000 patient test requisitions and performs about 10,000 tests. The unexpected loss of telecommunications with the data server at HIP headquarters meant that CLS would be receiving specimens at the lab and would need to enter the data on the paper requisition in order to run the test and generate a paper report.

But that was not the only challenge. The entire city of New York was in chaos. Transportation access to and from Manhattan was closed or severely limited. People coming in to work at the lab were stunned. Some had friends and relatives working in the towers or downtown.

"In the midst of all the confusion that morning, we convened a contingency planning meeting," said Dr. Pearlman. "Although our lab is staffed 22 hours per day, the main work shift is noon until two a.m. That gave us some time to develop a contingency plan and have it ready as people reported to work throughout the day."

Redirect Med Techs

"First, we decided to get as many people as possible working on data entry to accession specimens," he noted. "To accomplish this, we used medical technologists and other trained positions. This did cause some delays in testing.

"In the following days, we had between six to eight temporary helpers. We used temps all the way through October 4, when telecommunications was finally reestablished with HIP's data server.

"Second, we immediately did triage on the specimens," he continued. "We identified STAT, pre-ops, and specimens with viability issues, such as CBCs and coags. These were accessioned and run on a priority basis. Tests considered 'non-essential' were held back and eventually referred to some labs in Brooklyn and Long Island. On an emergency basis, they did a great job and were most helpful.

"Third, we revised our courier arrangements. This was a challenge all its own, as bridges and tunnels to Manhattan were closed. It was impossible to use our regular courier routes. We also had the couriers hand-deliver paper reports of test results."

Data Link Remained Down

At weeks' end, transportation access around the New York area was restored, except in downtown Manhattan. But the data link remained down and telephone lines continued to be a problem. "By the following Monday, we had caught up with all the testing," recalled Dr. Pearlman. "However, with no access to the data server, we were totally dependent on hand entry of data from the paper requisitions. We had to hand-enter data for three weeks, until the connection with the data server was restored."

Because CLS outsources anatomic pathology (AP) work, accessioning and processing of these cases was unaffected by the loss of the data link to HIP's computer server. "Our courier system was able to maintain timely delivery of AP specimens to our participating pathology groups," observed Dr. Pearlman, "so this work flow continued without interruption."

CLS continues to "mop up" lots of details left over from the crisis triggered on September 11. "Our normal telephone service is still unreliable," he explained. "During the day, as the phone company works to restore telephones in lower Manhattan, our lines will unexpectedly cease to function. People calling in will only get a busy

signal. An hour or two later, our phones will function perfectly again."

Overall, Dr. Pearlman gives high marks to the the management and staff of CLS for its successful response to the emergency. "Lots of our people made heroic efforts in the days following the disaster," he said. "If it wasn't for the sadness over this event, we'd be celebrating our response to a very challenging time. At the least, we are looking for an appropriate opportunity, in the near future, to formally recognize and thank everyone for their contributions."

As CLS absorbs the management lessons learned from this disaster, certain changes are planned. "We are meeting next week to refine our contingency plans," observed Dr. Pearlman. "Certainly these events raise questions about where the computer server is located and how our lab is connected to it."

Because CLS is about to undergo an LIS conversion, there will be the opportunity to revise some of the data processing infrastructure. "We were scheduled to begin our conversion to the **Soft Computer** LIS system on September 13," noted Dr. Pearlman. "That will now start on October 18. Armed with our new experiences, we will definitely have some additional things to accomplish as part of this LIS conversion."

Most Disrupted By Attacks

THE DARK REPORT believes that Centralized Laboratory Services probably suffered the most operational disruption of any American lab as a direct result of the terrorist acts on September 11. However, like labs around the country, CLS rose to the occasion and maintained a high level of testing services for its physicians and patients. **TDR**

Contact Eugene S. Pearlman, M.D. at 718-786-2300.

CLS's Testing Fulfills A Different Mission

WHAT MAKES Centralized Laboratory Services (CLS) of New York City unique among the nation's laboratories is that it is organized to serve a different mission.

"We are owned by Health Insurance Plan of New York (HIP)," said Eugene S. Pearlman, M.D., Medical Director of CLS. "Our job is to provide testing for the 1 million beneficiaries of HIP, who are primarily government employees, fire fighters, police, and their families.

"Our mission is to provide high quality lab testing at the lowest possible cost. We are also directly involved in managing test utilization to favorably influence outcomes and manage the cost of health services," added Dr. Pearlman.

Because CLS serves a targeted population, its data system is organized to take a very high proportion of electronic test requisitions and report an equally high proportion of test results electronically. It was this reliance on electronic ordering and reporting which made the lab vulnerable to the loss of the telecommunications link to HIP's data server.

Another interesting difference at CLS is extensive use of reflexive testing. "Our HMO pays for all testing services," commented Dr. Pearlman. "Thus, Medicare regulations are not applicable for our beneficiaries. This allows us to design reflexive testing algorithms which maximize quality of care and reduce overall costs.

"We do lots of reflexive testing," he added. "Since most of our specimens arrive in the lab by late afternoon and early evening, reflexive testing at the second and third levels is done in the early morning hours. This enables us to provide the physician with a complete test report when he starts the day in his office."

CEO SUMMARY: *All laboratory managers and pathologists face the same challenge: do more testing with less money. This challenge is further complicated by the fact that there are inadequate numbers of trained laboratory professionals available to staff the nation's laboratories. Now, early-adopter labs are turning to management methods developed outside of healthcare as a way to solve these problems and move laboratory operations to a higher level of performance and quality.*

HOSPITAL LABS ATTACK OPERATIONAL CHALLENGES

"Lean" Management Helps Bay Care's Lab Boost Quality

ONE-BY-ONE, a small handful of early-adopter laboratories are introducing management methods developed by manufacturing companies into their daily testing operations.

These management systems are designed to simultaneously: 1) maximize the quality of output; 2) reduce cost by maximizing the productivity of labor, equipment, and work processes; and 3) keep the lab focused on meeting the needs and expectations of its users (customers).

The most recognizable names for these management systems include ISO-9000, "lean" management, and Six Sigma. They are the latest generation of management systems first developed during the 1970s and 1980s from the work of quality management gurus such as W. Edwards Deming, Joseph Juran, and Taiichi Ohno.

Pressures On Lab Managers

Lab administrators and pathologists face ongoing pressures to perform ever-greater volumes of lab tests at declining levels of reimbursement. At the same time, the growing shortage of trained medical technologists is forcing lab managers to think creatively about how they organize and operate their clinical laboratories.

Collectively, these pressures are motivating an ever-growing number of lab administrators to adopt and introduce management methods from manufacturers into their clinical laboratories. In Tampa, Florida, the laboratory division of **BayCare Health System** recently completed its first operational project that incorporated lean manufacturing and Six Sigma methods.

"At BayCare, we have nine hospitals, seven laboratories (doing 4 million tests per year), and five LIS systems," said Victor Hruszczyk, BayCare's Vice President of Laboratory Services. "Like most multi-hospital systems, we want to fully realize all the potential economies of scale that come from lab consolidation and integration.

"Also, our health system is proud of the fact that there are ten 'Top 100 Awards' for quality management among our nine hospitals," he added. "In fact, **Morton Plant Hospital** is the only hospital in the nation recognized as having achieved 'Top 100' status in *all* operational categories. Because of these management accomplishments, our administration is more receptive than most to applying proven quality management techniques to improve outcomes."

The BayCare lab got into its lean management/Six Sigma project after approaching **Ortho-Clinical Diagnostics** (OCD), a division of **Johnson & Johnson Co.**, to ask for help in improving blood banking operations. "Because of OCD's presence in the blood market, we felt they had expertise which could help get us to the next level of efficiency," observed Hruszczyk.

"However, after a review of the project, OCD suggested that it might be more appropriate to tackle a lab operations improvement project in the chemistry section," he explained. "This would allow us to teach the new management methods as part of the project implementation, thus creating a knowledge base among the laboratory staff that would support more ambitious lab improvement projects in later phases, including our system-wide blood banking services."

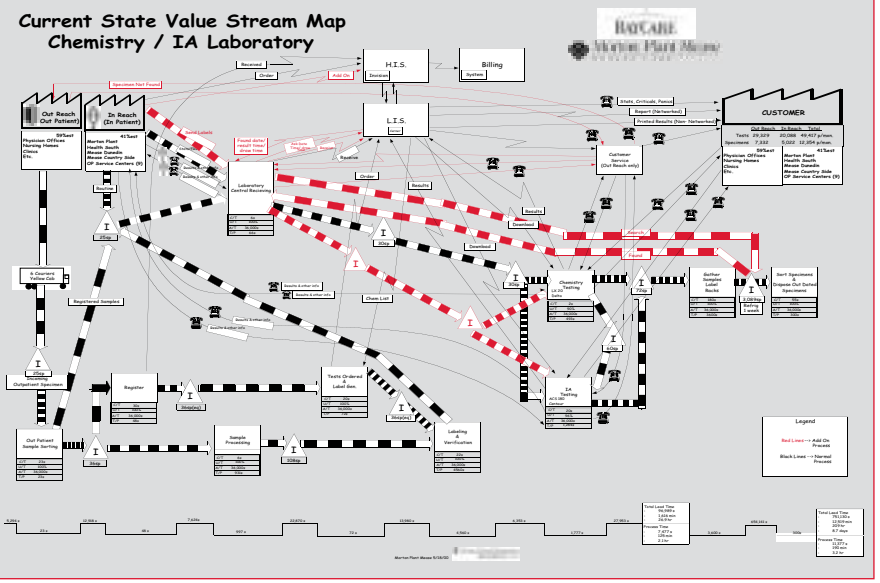
The business relationship between BayCare Health System and Ortho-Clinical Diagnostics represents a different business model between vendor and customer. Like many healthcare suppliers, OCD is looking to add value in non-traditional ways. To support the sale of instruments, reagents, and other healthcare products, OCD introduced a management consulting service for its hospital system and laboratory customers.

Major Commitment To Quality

"Within Johnson & Johnson, there exists a corporate-wide commitment to implement

Workflow in Chemistry Section "Before" Shows Inefficiencies and Muda (Waste)

"This is a map of the work flow processes in our chemistry department. This map helped us identify opportunities to streamline and speed up the testing process and to also enhance quality. The different colors represent things like specimen flows, information flows, and the like," stated Victor Hruszczyk, BayCare's VP of Laboratory Services. "All the confusion represented by these lines illustrates the opportunities for simplification."



the management methods of 'lean' and Six Sigma," said James Ellis, Director of Laboratory Consulting at Ortho-Clinical Diagnostics. "Management and staff at all levels are undergoing training in these methods. It was logical to extend this expertise to OCD customers. The BayCare chemistry laboratory project is a good example of this business service."

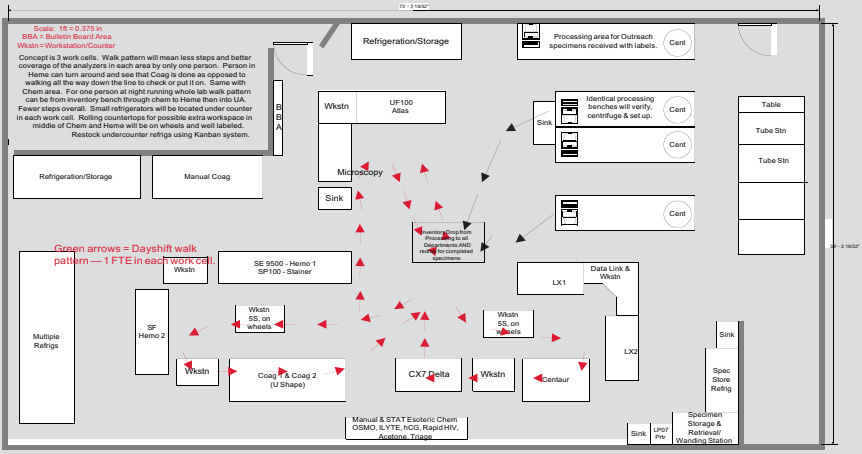
BayCare was a beta lab site for the OCD consulting effort. OCD identified, in advance, the amount of money that could be saved if the project was implemented per plan. To maintain compliance with Medicare and other guidelines, the agreement was structured so that OCD did not identify, in advance, the specific operational changes it would implement to generate the projected savings.

"It was quite an experience to see the OCD people arrive for phase one of this project," noted Hruszczyk. "A host of black belts and tool masters arrived, well-equipped with video cameras and stop watches. Some of the lab folks giggled a bit, but BayCare's quality administrators already knew about black belts and were both impressed and excited at the opportunity to work first-hand with industry-certified black belt quality specialists. This gave the OCD team heightened credibility and morale in our lab soared from this point forward."

The study phase lasted one week. The goal was to evaluate existing work

Workflow in Chemistry Section "After" Boosts Productivity and Improves Quality

"This value stream map shows how 'lean' and Six Sigma management techniques helped us streamline our workflow," noted Victor Hruszczyk, BayCare's VP of Laboratory Services. "Our intent was to consolidate work stations in the chemistry department and to achieve cross-training. The end result was a much more efficient operation."



flows in the chemistry department. This information was used to generate a "value stream map," similar to a flow chart. "This map represented the current state of the lab," noted Hruszczyk. "My first reaction was how fundamentally more advanced this approach was over the early quality methods many of us laboratorians used in the 1980s and early 1990s.

"We had seven primary goals for this lab operations improvement project," he noted. "1) to identify and implement opportunities for cost reduction; 2) to simultaneously improve the quality of lab test results; 3) to improve work flow from specimen arrival to storage; 4) to minimize the need for movement within the laboratory; 5) to shift and concentrate labor on activities which add maximum value; 6) to minimize lab renovation costs (that became a big issue); and 7) to teach the laboratory team how to understand and apply the tools of lean thinking and Six Sigma.

"The study phase is designed to identify the 'current state' of the lab operation," said Hruszczyk. "Further, we were introduced to an important Japanese word: muda, which means waste. These management methods are constantly focused on identifying sources of muda—waste—then eliminating them to lower costs and improve quality."

"During this project, we learned to identify seven sources of waste in the lab (see table on page 14)," he recalled. "For example, take the category of unnecessary motion. The video cameras identified that, twice every night, our chemistry techs had to leave their instruments, walk down a hall, fetch controls from a refrigerator, then return to run those controls on the instrument," he explained.

"OCD's team made the obvious recommendation 'why don't you simply put a refrigerator close to the instruments!' Simple enough and an obvious win for us," added Hruszczyk, "but until the lean thinking approach, it had escaped our notice.

"Another source of waste was our existing quality control procedures," he continued. "Pre-project, we were doing about 220,000 quality control (QC) comparison tests per year. That will shrink to 64,000 tests per year as we implement all the identified improvements, a 70% reduction. And remember, even as we better utilize QC testing, quality of our overall testing is improving."

"We also looked at turnaround time," he noted. "OCD compared our metrics with their data base. We had a reasonable TAT of 32.6 minutes for the overall emergency department testing," declared Hruszczyk. "Our hospital standard was 90% attainment of a 60-minute cut-off, which we met quite frequently. After deliberation, J&J encouraged us to establish a new best practice of 95% compliance with a 45-minute cut-off."

Concept of Six Sigma

Hruszczyk stated that lean thinking methods must be matched with Six Sigma techniques. "Six Sigma is a concept that says your goal is to achieve work processes that run at less than 3.4 defects per million. This is a startling metric. Six Sigma allows you to look at events within your value stream and understand where improvements can occur. Once you implement improvements, Six Sigma allows you to measure and quantify the impact of those improvements.

"It's a tool that makes management much more precise for the entire lab staff," noted Hruszczyk. "It's a scientific method that uses statistics to evaluate the process and measure outcomes," he continued. "For my management purposes, this analysis of the lab now allows me to assess operations from the 30,000 foot-level, then drill down to any desired level of detail."

Concept Is Validated

Part of OCD's initial assessment included a SWOT analysis (Strengths, Weaknesses, Opportunities, Threats)," stated Hruszczyk. "On the strength side, it showed that our lab was already quite efficient and we were client/customer focused. On the weakness side, our basic pre-analytic work processes could stand improvement, our lab layout needed renovation, and we were under-utilizing our LIS (**Cerner**)."

Labor productivity at BayCare's lab division was greatly boosted as a result of applying lean/Six Sigma management principles. "With the shortage of trained medical technologists, the positive impact of this improvement project on lab labor was significant," observed Hruszczyk. "We studied how the proposed renovations would affect workflow during both day and evening shifts.

"Our goal was to insure that we achieved a $300,000 annual savings from the different improvements after implementation," he said. "Proposed changes would reduce the existing staff of 16 medical technologists by five, or 31%. These changes would immediately boost yearly productivity per med tech FTE from 86,000 tests to 125,000. Those med techs freed from the chemistry department would be used in other areas of the lab.

"Our staff understood from the start that that these changes were not eliminating people, but giving them the opportunity to make a greater contribution to the lab while allowing us to bring more tests into the main lab," recalled

Seven Wastes of Ohno*

(Originally Applied to Manufacturing of Physical Products)

"Lean" principles of management center around the identification and elimination of seven specific causes of waste, originally described by Taiichi Ohno, of **Toyota Motor Corporation** in Japan. At BayCare Health System in Tampa, Florida, Victor Hruszczyk, Vice President of Lab Services, adapted Ohno's list to better reflect sources of waste in clinical laboratory operations. Such waste—known by the Japanese word "muda"—is the source of quality problems in testing and unnecessary laboratory costs.

Taiichi Ohno's 7 Sources of Waste:	Victor Hruszczyk's Laboratory Equivalent
1. Overproduction	Inappropriate utilization
2. Waiting	Waiting (turnaround time)
3. Transportation	Transportation
4. Inappropriate Processing	Errors in orders (e.g. ABN, MSP)
5. Unnecessary Inventory	Duplication
6. Unnecessary Motion	Unnecessary Motion
7. Defects in the product	Incorrect results

* Ohno, Taiichi; *The Toyota Production System: Beyond Large Scale Production* [Portland, Oregon: Productivity Press, 1988], pp 19-20

Hruszczyk. "Across the nation, 65% of the medical technologists are older than 45 and recruiting additional technical staff in the Tampa Bay area is very difficult. With specimen volume steadily increasing, we need all these people to process the work and continue to expand the menu of testing services we offer our physicians."

Concluding Comments

Upon completion, the chemistry project generated direct annual savings that came very close to OCD's original projections. "We achieved 90% of those objectives," said Hruszczyk. "However, there were unanticipated expenses involving construction costs to the older building which houses the lab. These were necessary to support the work flow redesign. If these construction costs are added in, we achieved about 45% of the original estimate.

"There are lots of unmeasurable benefits as well," he continued. "Our performance improvements in chemistry department service and turnaround times now allow us to meet the needs of chemistry test users without the need for satellite laboratories. We've also been able to reassign the medical technologists freed by this chemistry work flow redesign project into other areas of the laboratory. That's allowed us to boost productivity and add more testing services.

"Overall, we've definitely learned a lot from this first quality management project," concluded Hruszczyk. "There is a place in the laboratory for 'lean' and Six Sigma methods. These are good management tools that we will continue to use." TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

It's a sign of the times for managed healthcare. **Pacificare Health System, Inc.** will offer its first preferred provider organization (PPO) health plan. the PPO is being marketed in California, Oklahoma, and Texas. Enrollment starts this month. Until now Pacificare's business model was solely built around a fully-capitated, provider-assumes-all-risk arrangement. But during the past 24 months, increasing numbers of hospitals and physician groups refused to accept capitated, full-risk contracts. This forced Pacificare to shift its business model away from capitation.

MORE ON: PACIFICARE

Here's one reason why Pacificare is abandoning its fully capitated-total risk business model. The **California Department of Managed Care** reports that only 44% of the state's more than 200 medical groups meet all financial solvency standards required by regulation. Below-cost reimbursement from HMOs is a major source of near-bankrupt conditions among many physician groups in California.

ONCOLOGY PPM EXITS THE BUSINESS

It's another nail in the coffin of the PPM (physician practice management) business model. **U.S. Oncology, Inc.**, based in Houston, Texas, announced a plan to allow its 50 or so oncology practices to buy back their independence at a big discount. Financing, secured by the practice's own accounts receivables, will be available to expedite the sale. U.S. Oncology, after abandoning the PPM business, feels it has a better future offering services in the oncology pharmacy market.

ADD TO: PPM PROBLEMS

After the collapse of large multi-specialty PPMs such as **MedPartners**, **PhyCor**, and **FPA Medical Management** a couple of years ago, it was believed that single-specialty PPMs were more viable. But the fate of the six pathology PPMs that received venture capital funding is instructive. Two of these, **Pathology Partners, Inc.** in Dallas, Texas and **U.S. Labs, Inc.** in Irvine, California quickly adopted a different business strategy entirely. Of the remaining four, **Inform DX, Inc.** (formerly **Pathology Consultants of America**) ended up acquiring financially-ailing **American Pathology Resources, Inc.**, (APR) and **PathSOURCE, Inc.** But, with its own financial problems, Inform DX was acquired last year by **AmeriPath, Inc.**, which continues to own and operate pathology practices in 21 states.

There's an executive search underway at **Specialty Laboratories, Inc.** of Santa Monica, California to find a new vice president of sales and marketing. The position opened up when John Littleton, the former VP of sales, resigned on September 28. Littleton was part of the executive team which generated strong revenue growth in recent years and positioned Specialty Labs for its successful initial public offering (IPO) last fall. Littleton says he intends to take a sabbatical through the end of the year before considering other opportunities in the laboratory industry.

That's all the insider intelligence for this report. Look for the next briefing on Monday November 5, 2001.

UPCOMING...

- *PART THREE: Purchasing Browser-Based Test Ordering/Reporting Systems—Secrets to Negotiate the Best Deal.*
- *Emerging Legal Threats for Anatomic Pathology: Five "Must Review" Issues.*
- *How Labs Are Organizing to Combat Biological and Chemical Weapons Attacks.*