Volume XI, Number 8 Monday, June 7, 2004

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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Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Cement Shortage, Oil Prices, and U.S. Healthcare

TODAY I AM GOING TO CONNECT CEMENT SHORTAGES and spiraling oil prices to intractable problems in our healthcare system. It's a way for me to show you an example of how globalization's impact to non-healthcare businesses can similarly affect the American healthcare system.

Climbing gasoline prices, now above $2.00 per gallon in many regions of the country, have been big news. That's because oil is trading above $40 per barrel, an all-time record high. But what's gotten less publicity is the shortage of cement in the United States. During 2003, the U.S. used 112.3 million metric tons of cement. Of that total, about 17%, or 19 million metric tons, is imported. Florida, a state which imports 40% of its cement, already has an acute shortage. Construction projects are delayed or shutdown because of the shortage. Spot shortages are occurring in other states, such as Texas, Louisiana, and South Carolina. Experts say the cement shortage is not due to inadequate supply, but because China—with its booming economy—has tied up the world's shipping lines to transport other building materials!

I consider this an economic development worth noting. Since World War II, the United States has been the unquestioned economic engine of the world economy. It imported a high proportion of the world's raw materials. That is no longer true. Oil prices are high because China is using significantly more oil each year. India's economy is growing, as is its appetite for resources like oil, cement, lumber, and steel. (Prices for the last two which have climbed 60% and 50%, respectively, during the past year). Even the Japanese economy, moribund for almost 15 years, has begun to grow at strong rates.

High prices and relative shortages of materials such as cement, oil, lumber, and steel signal that the United States is no longer the absolute, dominant influence on the world's economy. China and India are serving notice that they have the demand—and the money—to pay for the resources needed for their countries' growth.

I predict the American healthcare system will soon feel competitive pressure from outside our borders. It will come as these countries become wealthier and compete for healthcare resources. Healthcare here may then be tugged into two directions. One is the international outsourcing of some clinical services. Two is the need to bid for equipment and consumables, leading to higher healthcare prices in the United States. TDR

Molecular Diagnostics' "Gap in Expectations"

Offering molecular tests to clinicians continues to be a financial challenge

CEO SUMMARY: This year's* Executive War College *provided strong evidence that the twin trends of molecular diagnostics and Lean management methods are taking root within the laboratory industry. Each is a trend in its infancy. Molecular diagnostics will require considerable time before it exerts substantial impact on labs across the country. In contrast, Lean management is expected to find much faster acceptance.

By Robert L. Michel

THERE ARE TWO EMERGING TRENDS in the laboratory industry. Each is powerful and will alter laboratory management in ways never before seen within our healthcare system.

The first trend is molecular diagnostics and its use by clinicians in patient care. The second trend is the adoption of quality management systems by laboratories, particularly those methods known as Lean and Six Sigma.

Each trend is in its infancy. For that reason, laboratories and pathology group practices have the opportunity to study and anticipate the impact each will have on laboratory management. However, the pace of adoption will be radically different for each trend.

These conclusions were major insights from the ninth annual *Executive War College on Lab and Pathology Management*, which took place on April 27-28 in New Orleans. In assessing the experience and recommendations of over 40 speakers, there were several clear and definitive themes. These themes emerged from the strategic thinking and clinical initiatives noted in presentations from several of the nation's leading laboratories and pathology group practices.

For example, molecular diagnostics is still taking baby steps when it comes to clinical applications of genetic and proteomic technologies. Most laboratories with active molecular testing programs today are national specialty testing laboratories or aca-

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

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demic/tertiary center laboratories. Only a handful of community hospital laboratories have established molecular testing programs.

Why is that only a relatively small number of laboratories currently offer molecular tests to clinicians? The answer is financial. These early-adopter laboratories report that reimbursement is barely adequate to cover the cost of tests based on molecular technology. In most cases, laboratories offering molecular tests to clinicians are subsidizing the cost of this testing through other sources, including grants, clinical studies, and direct-to-consumer offerings, such as paternity testing.

Collectively, when addressing this topic, most speakers at this year's *Executive War College* predicted that molecular diagnostics will not take off until reimbursement for new molecular tests reaches levels which adequately cover a laboratory's full cost of offering such testing.

Who Will Pay?

Sufficient reimbursement was the number one strategic concern expressed by every speaker involved in clinical molecular testing programs. Even in cases where payers agree to cover certain molecular assays, the reimbursement approved for those tests is sometimes too meager to sustain a lab's molecular testing program.

The other major stumbling block in the field of molecular diagnostics is the operational complexity of establishing and running such a program. Equipment is expensive. Technical skills required to perform these tests are in short supply, making the labor component of molecular testing both expensive and difficult to recruit.

An additional hurdle is the time and expense required to educate physicians about new molecular lab tests. Experienced laboratories report that physician education is a key factor in the success of a molecular test. Physicians must know when it is appropriate to order the test, how to interpret and act upon the results, and how to properly follow-up the initial diagnosis with appropriate tests for monitoring and measuring therapy. To accomplish these goals, laboratories must devote time, manpower, and resources into physician education. That is another factor in making molecular testing an expensive proposition for most community hospital laboratories.

Potential For Rapid Change

It was the collective sense of most speakers that clinical molecular testing is a difficult, financially-challenging, and complex line of testing to offer in today's clinical environment. Along with this observation was invariably a caveat—molecular diagnostics has the potential to become, almost overnight, the must-do for every laboratory. That would be true if a new test technology changed the standard of care.

As it comes of age, there is wide agreement that molecular diagnostics has the potential to transform laboratory medicine. There is a parallel trend which has comparable potential to radically transform laboratories. That trend involves the implementation of quality management systems, particularly those known as Lean and Six Sigma.

At this year's *Executive War College*, several strategic case studies highlighted the experience of the first major laboratories in the United States to use Lean methods to radically make over their high volume core laboratories. **Fairview Health Services** of Minneapolis, Minnesota and **West Tennessee Health System** of Jackson, Tennessee introduced Lean into their core chemistry-hematology laboratories on a 16-week implementation

schedule. Unlike earlier quality management systems like TQM (total quality management) and CQI (continuous quality improvement), Lean and Six Sigma can create substantial improvement in a short amount of time.

In fact, Rick Panning, President of Laboratory Services at Fairview, observed that all levels of administrators in this eight-hospital health system had regularly undergone quality management training for almost fifteen years. Fairview's senior health administration was already committed to quality management. It turned to Lean as a way to accelerate the results generated by quality projects.

Achieving Faster Results

Fairview believed Lean techniques could compress the time required to identify opportunities for improvement and cost reduction, and the time required to implement those changes. The Lean project in its first hospital laboratory was actually the "proof of concept" project. Once it was validated that Lean techniques required just three or four months to deliver major gains, Fairview Health Services proceeded to schedule Lean projects in all its hospital laboratories. It also began to introduce Lean into other clinical areas, such as the emergency department, radiology, pharmacy, etc.

West Tennessee Healthcare of Jackson, Tennessee told a similar success story to the *Executive War College* audience. Gains of 50% in the average turnaround time for inpatient testing, productivity improvement of 60% for laboratory labor, and comparable gains in quality were a few of the outcomes described by Leo Serrano, Administrative Director of Laboratory Services at this innovative health system.

The effectiveness and relevance of Lean management methods in labora-

Molecular Testing Hits Kaiser In a Big Way

EVERYTHING IS ON A BIG SCALE AT Kaiser Permanente Northern California's regional laboratory. It accessions 28,000 patients daily. So when Kaiser administration wanted to introduce a molecular test into general clinical use, the impact on the regional lab was huge.

"Our lab's molecular hurricane was triggered by the new cervical cancer screening guidelines," said Gene Pawlick, M.D., Director of Kaiser's regional laboratory in Berkeley, California. "When Kaiser decided to embrace the new guidelines, we were told to gear up to support this new clinical standard of practice.

"It meant that our laboratory, which had performed about 5,000 of **Digene's** HPV tests in 2003, would be performing 400,000 DNA with Pap® tests annually by the end of 2004," explained Pawlick to a fascinated *War College* audience. "Fortunately for our laboratory, administration also declared that our laboratory budget would be increased to accommodate the additional volume of this expensive test.

"But that still left us with the challenge of preparing our laboratory to perform these 400,000 tests," he added. "We've been scrambling to put the equipment and medical technologists into place to support this volume of testing.

"Among the lessons and insights I want to share with you is this: at any time, a new molecular technology has the capability of changing long-standing clinical practices—literally overnight! That's a serious threat to a laboratory, particularly if Medicare, Medicaid, and private payers are slow to respond with coverage and appropriate levels of reimbursement. In our laboratory, we now better appreciate the importance of tracking new molecular technologies as they find their way into diagnostic testing," advised Pawlick.

Lean Boosts Two Labs: It Eliminates STAT Tests

CAN A LEAN PROJECT DELIVER BIG GAINS to a laboratory which is already recognized as a top performer? Two innovative laboratory directors agree: the answer is yes!

"It's been seven months since our first Lean project in the core laboratory at **Southdale Hospital**," observed Rick Panning, President, Laboratory Services at the eight-hospital Fairview Health Services in Minneapolis, Minnesota. "We cut our average turnaround time from request to verified result by 50% in the first 16 weeks of this project. "However, in the months since that project was completed, we've continued to improve our service consistency. There are no longer STAT tests in this laboratory," said Panning. "Moreover, feedback from nurses and physicians is positive. Individuals from our lab's first Lean team are leading the introduction of Lean methods into other clinical areas around the hospital."

"We've achieved some remarkable gains," declared Leo Serrano, Administrative Director of Laboratory Services at West Tennessee Healthcare in Jackson, Tennessee. "TAT for specimen collection to receipt in the lab fell from an average of 27 minutes to 6.3 minutes! In the eleven months since the start of our first lean project, there is not one documented case of a patient ID error attributable to a laboratory employee. Our lab is now organized around single piece flow, not batch work. We are believers in Lean management methods."

tory settings was solidly demonstrated by both presentations. These were two of the nation's better-managed hospital laboratories—yet each harvested gains of 50% or more in just the first 12- to 16-week project. The message was not lost on the audience.

Because Lean and Six Sigma management systems can deliver substantial cost reductions, I believe that laboratory directors and pathologists will embrace these solutions with less resistance than might have been true of when TQM and CQI were the buzzwords of their hospital administrators.

There are already signs that the Lean trend is gathering momentum within the laboratory industry. A growing number of hospital laboratories are launching Lean and Six Sigma projects. I am confident that, if those projects are done with the help of experienced and knowledgeable Lean experts and Six Sigma black belts, they will deliver results comparable to those shared on these pages. As word of such successes gets out, there will be both an incentive and a pressure for other laboratory leaders and pathologists to generate similar results from their laboratory organization.

Fast-Moving Trend

Publicity about these successes insures that the trend for laboratories to adopt Lean management methods will grow. That is why I predict that the Lean trend will move through the laboratory industry at a much faster pace than the molecular diagnostics trend.

Having looked individually at the twin trends of molecular diagnostics and Lean, an interesting question presents itself. What if, on their separate, but parallel tracks, molecular diagnostics and Lean interact with each other in unexpected ways? Each promises paradigm-shifting improvements in laboratory operations and clinical capabilities. Could these two trends, when mixed in one lab, morph into an exponential agent of change?

Imagine that outcome! It could mean that laboratories offer clinicians an extraordinary array of sensitive new molecular tests—delivered in a low cost service package. It would be the equivalent of today's $500 Pentium PC with the 50-gigabyte hard drive. Hard to imagine in 1984, but a reality in 2004! TDR

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Congress Holds Hearing On Hospital Lab Fiasco

CAP's lab inspection process is criticized by Maryland State Health Secretary

CEO SUMMARY: Problems at the laboratory of Maryland General Hospital came under scrutiny at a recent Congressional hearing. There was plenty of criticism and embarrassment for several entities which should have detected the problems and reacted to the situation more effectively. Serious questions were asked about how and why so many safeguards failed to detect and correct this situation.

IT WAS A CONGRESSIONAL HEARING marked by plenty of criticism about failures of various inspection teams to identify major problems in the laboratory at Baltimore's **Maryland General Hospital** (MGH) for as long as two years.

On May 18, 2004, the House Criminal Justice, Drug Policy, and Human Resources subcommittee conducted a three-hour session to hear testimony from the Maryland State Secretary of Health, a representative from the **College of American Pathology** (CAP), Medicare officials, FDA officials, and a whistleblower from the laboratory. Testimony was also given by an executive from **Adaltis U.S.**, manufacturer of the instrument which produced unreliable results for HIV and HCV during the 14 months it was operated by the Maryland General Hospital laboratory.

"It would be a terrible mistake to categorize this as an isolated incident," declared Nelson J. Sabatini, Maryland State Health Secretary during his testimony. "I believe that the Maryland General experience is merely a symptom of a system failure."

Sabatini has harshly criticized the laboratory inspection and accreditation process. It is now known that, during the years 2002 and 2003, the MGH laboratory had serious operational problems. Yet, following a CAP inspection of the laboratory in April 2003, CAP give it the highest rating: "accredited with distinction."

DOH Inspections

Although Sabatini's criticism is valid on many points, it does reflect political sensitivities. Separate inspection teams from both the State of Maryland's **Department of Health** (DOH) and the College of American Pathology made multiple visits to the MGH laboratory during the years 2001 through 2003. None of these inspections uncovered serious problems.

"I am not proud of what we did," admitted Sabatini. In fact, it was not until a second whistleblower from the laboratory notified the DOH that its inspectors finally uncovered the wide-

spread and ongoing problems within the MGH laboratory.

"Patient safety is ultimately a government responsibility, but we have subcontracted it out," observed Sabatini. He was referring to the arrangement whereby the **Joint Commission on Accreditation of Healthcare Organizations** (JCAHO), CAP, and similar industry organizations conduct inspections under an agreement with the federal government.

Inspections By Peers

During his testimony before the subcommittee, Ronald B. Lepoff, M.D., representing CAP, admitted that CAP's two accrediting inspections, during 2001 and 2003, were performed using inspectors from other laboratories around Greater Baltimore. He asserted that CAP's inspectors, although peers, maintained independence and this had been demonstrated during the decades that the CAP laboratory accreditation process has been in effect.

He also characterized the inspections conducted by JCAHO and CAP as "collegial" and "leisurely" and not likely to uncover serious deficiencies.

Sabatini responded to Lepoff's comments by noting that self-inspections were one factor in the failure of the system to detect serious failings with the MGH laboratory. He also characterized the inspections conducted by JCAHO and CAP as "collegial" and "leisurely" and not likely to uncover serious deficiencies.

The potential harm to patients caused by the laboratory's failings was highlighted by another witness, the President of **University of Maryland Medical System** (UMMS). UMMS owns Maryland General Hospital. Edmond F. Notebaert, UMMS President, revealed the results of retesting to date. MGH offered retests to approximately 2,100 patients whose HIV and HCV tests were performed during the 14-month period that unreliable results were generated. Of those retests done as of the hearing date, two patients originally tested negative for HIV now test positive. Three patients who originally tested negative for HCV now test positive.

The failures within the laboratory at Maryland General Hospital are unprecedented. THE DARK REPORT can find no comparable incident involving a hospital laboratory in the past two decades. This magnitude of failure in a hospital laboratory is a unique event, with significant consequences. This type of lab failure has the same potential to spook the public as the crash of an airliner full of passengers.

Violated Basic Lab Tenets

What is most disturbing is that this is an example of how, for almost two years, the laboratory of a 243-bed urban hospital can operate in violation of almost every established principle of operational integrity and quality control! During this time, laboratory staff and laboratory administration knowingly violated the most basic tenets of their training.

The MGH laboratory debacle is a reminder to every laboratory manager and pathologist of how quickly public trust in a laboratory can evaporate. THE DARK REPORT can speculate that Maryland General Hospital is surviving this crisis because it is a community institution.

But what if these events had unfolded in a commercial lab company? How would the public respond to news that this lab company had failed to report accurate test results? It is highly likely that public response would force government regulators to shut down a for-profit lab company that had failed as spectacularly as the laboratory at Maryland General Hospital. TDR

Outcomes Update

CalPERS Drops 38 Hospitals From Its Preferred Network

Big healthcare buyer says excluded hospitals price services 60% to 80% higher than peers

IF CALPERS HAS ITS WAY, 38 hospitals and 17 physician groups will no longer be able to provide services to its healthcare network.

On May 19, 2004, the **California Public Employees' Retirement System** (CalPERS) announced a list of providers that it was excluding from its provider network for 2005. The news was a bombshell in California and nationally, because CalPERS is seen as a source of innovation which is rapidly copied by other employers and health insurers.

The hospitals excluded from the 2005 provider network are considered to be high-cost outliers. CalPERS, and its network administrator, **Blue Shield of California**, estimate the move will save the plan between $25 million and $50 million next year. This action will affect the care of approximately 415,000 CalPERS members.

High-Cost Outlier Claims

Hardest hit among the 22 hospitals targeted in Northern California is **Sutter Health**. It operates 26 hospitals and CalPERS wants to exclude 13 of those hospitals because of their high costs. Blue Shield claims these hospitals cost between 60% and 80% more than comparable hospitals. Sutter officials deny this. Because Blue Shield has not released the data it uses to make this claim, there is no way to challenge that estimate.

CalPERS is attempting to control the increase in the cost of its healthcare benefits. During the past three years, CalPERS' health insurance premiums have risen 57%! It provides health benefits to 1.4 million public employees, retirees, and their families.

What makes this a national story is the move by a major healthcare buyer to exclude providers from a network because of claims that they have "excessive charges." By taking this move, CalPERS is limiting the choices of health providers available to its members. Health industry experts believe this may encourage employers in other regions of the United States to identify "high-cost" hospitals and either exclude them from their employee's provider network, or charge employees who use these hospitals a higher deductible or out-of-pocket fee.

Laboratory directors and pathologists can consider this development to be another step on the road to measure provider outcomes and the cost-effectiveness of their health services. THE DARK REPORT interprets CalPERS' action as a significant signal that healthcare buyers are ready to become more selective in deciding which physicians, hospitals, and laboratories will be part of their provider network. It is early warning that laboratories and pathology groups should take active steps to improve outcomes and reduce their costs. TDR

NEWSMAKER INTERVIEW

"When a hospital or laboratory goes 'paperless', it's no longer 'business as usual' for pathologists."
—Bruce Dunn, M.D.

NEWSMAKER INTERVIEW

Pathologist Activities Evolve In VA's "Paperless" Hospitals

Essential tools become the "Three Cs": computer, cell phone, and car

CEO SUMMARY: One outcome of the **Veteran Administration's** (VA) ongoing effort to create a totally-integrated information system was to give the laboratory increased capabilities to enhance diagnostic testing services. It's also changing the way pathologists practice laboratory medicine and support clinicians. In this exclusive interview, Bruce Dunn, M.D., Director of Pathology and Laboratories for the VA's VISN 12, provides provocative insights into how and why his laboratory organization has gone "virtual." He offers tangible evidence that telepathology and other tools will break down geographical constraints and give pathologists the ability to support clinicians across vast distances. This interview was conducted for THE DARK REPORT by June Smart, Ph.D.

TDR (THE DARK REPORT): After the **Veterans' Administration** (VA) went "paperless" several years back, fundamental changes took place to your daily routine as both a laboratory director and as a pathologist. How would you characterize this situation?

DUNN: When a hospital goes paperless, it's no longer "business as usual" for pathologists and laboratory services. In the all-electronic environment of our VA hospitals and clinics, pathologists have added three essential 'Cs' to their toolbox: computer, cell phone and car. Mobility and agility are now essential attributes for our pathologists.

TDR: Wasn't that an unexpected consequence from the VA's move to an all-electronic information system within its hospitals and clinics?

DUNN: It is! The different things I now do as a pathologist each day are directly linked to the all-electronic world now found in every VA hospital. To understand this change, it is necessary to explain certain events within the VA.

TDR: Please do.

DUNN: These major changes began in the mid-1990s, when the VA decided to move to a PC-based information system. That's when my personal computer revolution began. Our laboratories used PCs to standardize policies and procedures across all sites. That happened during VISN 12's laboratory consolidation phase, which involved the laboratory services for eight VA hospitals in our region, encompassing Wisconsin, Northern Illinois, and Iron Mountain, Michigan.

TDR: Was that the first step in what became your paperless laboratory?

DUNN: Yes. Even while this was happening, the VA was rolling out an internal data network. It also integrated the clinical data bases and implemented a computerized patient record system (CPRS). The CPRS is connected to the integrated clinical databases. As a result, all our documents became electronic. The laboratory became much more efficient at moving information. Today, our Virtual Private Network (VPN) allows access to a variety of information, including patient charts and email. Tools like PDAs, USB drives, and laptops enhance the overall effectiveness of what we do in the laboratory.

TDR: Is this why your pathology duties evolved to rely on your "three Cs": computer, cell phone, and car?

DUNN: That's one outcome. The VA's electronic information infrastructure has, in many ways, transformed us into a virtual lab operations team within a virtual laboratory organization. The computer played a major role in allowing us to consolidate laboratory testing services. The computer now allows us to provide all sorts of clinical services, in real time, from any site within the VA. Earlier this year, remote access via the Web was enabled. Our pathologists, even when they are away from any VA facility, can use the Internet to conduct clinical and operational business.

TDR: That is a change.

DUNN: As clinical pathologists and anatomic pathologists, the VA's computer network unshackled us from specific desks and specific offices. On any given day, regardless of where a pathologist is working within VISN 12, he/she has immediate access to patient data through the CPRS. A legible chart is presented in a tabbed format similar to our previous hand-written charts. It is organized in a Windows-based format, making it surprisingly easy to navigate.

TDR: Did the CPRS system change how clinicians used information, ordered lab tests, and received lab test results?

DUNN: VA physicians are mandated to write their own orders in CPRS and to enter their own typewritten notes. Among other things, a physician entering his/her orders directly into the CPRS decreases errors that might be introduced by having ward clerks enter orders. Another strong point of CPRS is that results from laboratory, radiology and other clinical areas are presented in a well-coordinated manner.

TDR: Do pathologists work within CPRS?

DUNN: Pathologists can enter notes into the chart as needed regarding blood utilization, coagulation consultation, or other issues. These notes are separate from actual lab reports generated in surgical pathology, autopsy pathology, cytopathology, etc.

TDR: As a laboratory director for multiple hospital sites, how has the paperless system influenced your practice patterns and daily routines?

DUNN: The first aspect is access to information. Each VA site has granted permission, as appropriate, for me to access data. That allows me to access CPRS and see relevant patient data, regardless of the VA site. In the past, if I needed to review the chart of a patient

with a possible transfusion reaction, it might take several days to get that chart. I now have immediate access to patient charts from any hospital.

TDR: That's certainly a benefit in providing faster support and answers to clinicians. How has imaging capability changed the practice patterns of your anatomic pathologists, who rely heavily on images?

DUNN: Big changes here when compared to the imaging capabilities of a traditional hospital. Our CPRS has a feature called Vista Imaging. This allows images of radiology films and pathology images to be stored in the patient record electronically. These images can be viewed from the provider's desktop, no matter where he or she is located in the hospital. It is useful for viewing cases directly and for presentations at tumor board. Pathology images are often matched with radiology images in these situations. The imaging capability is also used within microbiology. There are regular instances when clinicians, discussing specific cases, refer to the stored digital images.

TDR: So this capability is supporting real-time consultations that use an electronic medical record to support the conversation between physician and pathologists. What else does it allow you to do differently in your pathology duties?

DUNN: Here's a great example. The system known as "Lab Information Manager" allows a pathologist to access the laboratory's "lab instrument manager" through a VPN connection from home. From outside the laboratory, we can now troubleshoot problems with instruments should they occur during off hours!

TDR: That's impressive. Tell me about new capabilities in telepathology within your VISN.

DUNN: Telepathology allows the VA hospitals in Iron Mountain, Tomah and North Chicago to have almost immediate access to generalist and specialist pathologists located off station. Moreover, we no longer mark cells on slides with ink and send them via the mail. Instead, we now send digital images—with the precise cells marked—instantly. The clinical impact of this has been significant. Immediate access to specialty care is now available to every VA site on the network. It was impossible to deliver this type of rapid specialty care before the all-electronic system used in our hospitals today. I should also add that all telepathology images are on a shared server, accessible by all sites. It is no longer necessary to send images point-to-point.

TDR: What other capabilities does telepathology bring to your laboratory?

DUNN: Telepathology provides us the capability to offer intraoperative frozen sections without having a pathologist physically at that site. We accomplish this by using a pathology assistant (PA) at that location. This is how we provide this service at the VA hospital in Iron Mountain. Our telepathology system has also been used by microbiology to identify enteric parasites (based on motility in wet preps), Blastomyces in gram-stained sputum, and Aspergillus fumigatus fruiting bodies in a clinical specimen.

TDR: Are there other clinical areas where telepathology has changed long-standing practices?

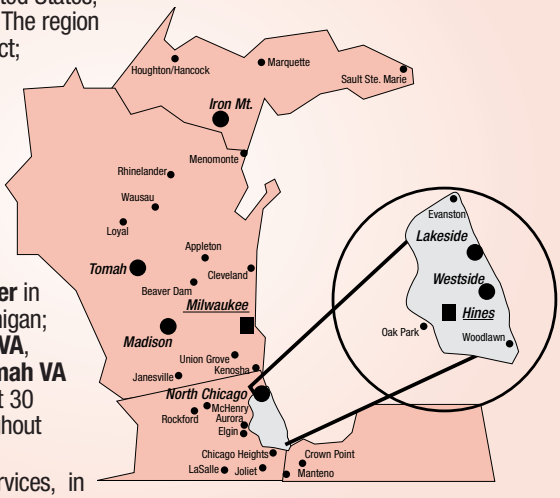
DUNN: It's being used to review and discuss problem cases in microbiology and hematology at Iron Mountain and in hematology at Tomah.

TDR: Weren't you also one of the first pathology groups to use telepathology for autopsies?

DUNN: Yes. We started using telepathology in 1996 when the pathologist at Iron Mountain retired and the closest VA laboratory was in Milwaukee, 220 miles away. At that time, I was watching

VA's "Paperless" Information Systems Change Pathologists' Daily Routines

IN A FIRST STEP TO CREATE AN INTEGRATED, NATIONAL HEALTHCARE SYSTEM, the Veterans Administration (VA) created the "Veterans Integrated Service Network" (VISN). It was formed in 1995 and created 21 regions across the United States, including Hawaii and Puerto Rico. The region served by VISN 12 is fairly compact; 300 miles north-south and 160 miles east-west. It covers seven hospitals. Two VA hospitals in Chicago were recently merged. They were **VA Chicago West Side** and **VA Chicago Lakeside**.



Rounding out VISN 12's hospitals are VA Hines Hospital and **North Chicago VA Medical Center** in Illinois; **Iron Mountain VA** in Michigan; **William S. Middleton Memorial VA**, **Clement J. Zablocki VA**, and **Tomah VA** in Wisconsin. There are also about 30 outpatient clinics scattered throughout VISN 12's region.

Within VISN 12, laboratory services, in tandem with the VA's paperless information system, has evolved into what Bruce Dunn, M.D., Director of Pathology and Clinical Laboratories, calls a "virtual laboratory organization."

telemedicine support radiology, nuclear medicine, psych, and pulmonary medicine. I championed this tool for laboratory use. With the help of the PA at Iron Mountain, I use telepathology to do autopsy cases from Iron Mountain. Images are then digitized and the autopsy cases presented to clinicians at Iron Mountain.

TDR: Has this become a routine?

DUNN: Yes. Presentations usually occur on Fridays. I am generally at the **VA Hines Hospital** in Chicago, about 300 miles away from the actual conference. This is all done electronically with the superb help of our PA.

TDR: Has telepathology contributed to enhanced clinical services in areas outside the traditional spectrum of anatomic pathology cases?

DUNN: It now plays a major role in microbiology didactic and case presentations at the VA hospital in North Chicago. Several years ago, North Chicago's microbiology services were consolidated into our Milwaukee laboratory. The Dean's Committee at the North Chicago affiliate was quite concerned. It did not appear to them that we could provide training to their infectious disease (ID) fellows. We now use telepathology as the training medium. ID staff and trainees love it. Another benefit is that we can present cases from throughout our VISN. Recently we presented a case of "culture negative tuberculosis" at Iron Mountain which turned out to be Blastomycosis. Milwaukee's ID staff now participate in the sessions. Telepathology has been the nidus which brought the ID sections at Milwaukee and North Chicago together to discuss cases among themselves. It's boosted the learning experience for everyone, including me!

TDR: Are there other uses for the digital imaging capability?

DUNN: When necessary, we digitize serum protein electrophoresis gels performed at Hines [in Chicago] to be read by our hematopathologist located at West Side, where we no longer perform SPEPs.

TDR: You had earlier referenced that the VA's choice of a PC-based information system changed how you personally perform your duties. I'm curious as to how other pathologists responded to the arrival of personal computers on their desks?

DUNN: The challenge was to encourage pathologists to become computer users and learn how it could help them practice medicine. This was one of our lab's biggest challenges in the move away from paper and onto electronic data. Both pathologists and med techs did buy into this new mindset. We've seen gains in patient care and patient safety as a result.

TDR: Do you have examples of how new computer capabilities changed either laboratory operations or clinical testing services?

DUNN: In Milwaukee, a medical technologist took it upon himself to learn the Access database program. He then developed a sophisticated database into which all labs put their quality management (QM) data. All data can be viewed by all sites. Graphs of key measures are generated automatically. This database is password-protected so only those with the need-to-know have access. It's allowed us to get real-time snapshots of how all laboratories in VISN 12 are performing.

TDR: Do you have an example?

DUNN: We track many things and Tuberculosis testing is among them. After we consolidated Tb laboratories to a single site (Milwaukee), it became important to track Tb smear turnaround time. Second shift staff at Milwaukee is trained to process the smears. These smears are ready to be read the next morning by our microbiology staff. From time of receipt in an off-site lab to the time when verified results are available in the computer requires about 24 hours. This exceeds the CAP standard, which requires results within 24 hours from receipt in the reference lab. Because of our integrated IT system and network, the consolidated micro labs (Hines and Milwaukee) and the Tb lab (Milwaukee) enter data directly into computers of the sending labs. No time is lost because results were sent to the referring lab and sat until that lab had time to enter them.

TDR: Any other interesting uses of your PC-based information system?

The challenge was to encourage pathologists to become computer users and learn to like how it helped them practice medicine.

DUNN: We developed an Access database with electronic reports of problems to **Quest Diagnostics Incorporated**, our single reference lab. Electronic validation of the reporting process with Quest is in progress. Quest has provided a black belt QM trainer from its Six Sigma program to work with us on this project. Other Access databases are used for Blood bank and the VISN infection control committee (chaired by yours truly). Many of our labs also use a local occurrence reporting and safety database which was extracted from the VISN QM database.

TDR: These examples certainly illustrate how much impact a paperless environment has had on the laboratory

and your pathologists. But I think this accomplishment is even more remarkable because this all happened even as the laboratories of VISN 12 cut unnecessary costs and became more productive. Please provide us some context for this accomplishment.

DUNN: Prior to consolidation, VISN 12's laboratory costs per patient averaged $230. This was in 1996. By 2003, our laboratory had reduced this to $150 per patient. That's a reduction of 35%. Consolidation involved the hospitals of 11 laboratories (seven based at hospitals and four based at outpatient clinics), standardizing equipment across all sites, and implementing uniform procedures. Reductions in laboratory staffing levels was accomplished through attrition.

TDR: What reduction of staff was accomplished?

DUNN: Overall, it shrunk by about 30%. However, during the past seven years, increased utilization raised the workload in the laboratory by 34%. Second and third shift volumes are up, which helped us gain economies of scale. Collectively, the combination of increased workload and reduced staff show that we've made impressive progress on boosting the performance of all the laboratories within VISN 12.

TDR: Earlier in this interview, you described your organization as a virtual lab run by a virtual team. Please explain.

DUNN: The structure of our laboratory today is the result of two unique developments. First, since the mid-1990s, the VA has been at healthcare's cutting edge with its success at moving so many clinical and administrative functions onto an integrated information system, accessible through either our internal network or the World Wide Web. Second, as this was occurring, the laboratories of VISN 12 were undergoing an extensive consolidation and integration process. As we changed long-standing procedures and work practices in our laboratory, we had the unique opportunity to move them away from paper and onto a computer.

TDR: Do you attribute your virtual lab to this unusual confluence of opportunities?

DUNN: In many respects, yes. How many hospitals in the United States are paperless? How many health systems can allow a physician to access, via intranet or Internet, a patient's full, electronic medical record? To my knowledge, the VA is unique in giving our laboratory the ability to configure our operations and our services around this capability.

TDR: What about the aspect of a virtual laboratory team?

DUNN: The VA's information network allows our pathologists, administrators, and laboratory staff to make contributions from any site within the system. On the IT side, VISN 12 laboratories rely a great deal on the efforts of Debbie Sieloff, MT(ASCP), chairperson of our Laboratory Information Management technical committee. Laboratory operations are guided by Tom O'Donohue, DLM, ASCP, Administrative Director of Pathology and Laboratory Medicine Service (P&LMS) for Southern Tier, and John Heffner, MT(ASCP) Administrative Director of P&LMS for Northern Tier.

TDR: Bruce, this is certainly a fascinating look into how a paperless health system allows pathologists to reshape their daily work patterns. Thank you.

DUNN: You're welcome! In closing, I would like to recommend that pathologists closely track how enhanced information technologies can improve their ability to provide enriched services to clinicians. That's certainly been our experience within VISN 12 here at the Veterans' Administration. TDR

Contact Bruce Dunn, M.D. at bruce.dunn@med.va.gov.

Federal Govt. Leading March to Universal EMR

Labs should heed announcements: healthcare needs to go fully digital

CEO SUMMARY: On April 26, 2004, President George W. Bush announced a new goal for the nation: an electronic medical record (EMR) for every patient within ten years. Last July, THE DARK REPORT predicted that the federal government would take the lead role in pushing healthcare to adopt a universal electronic medical record. Introduction of the universal EMR will create new winners and losers among the nation's laboratories.

EVERY LABORATORY AND PATHOLOGY group practice should closely track the drive to convert the American healthcare system to a universal electronic medical record (EMR).

The declaration on April 26, 2004 by President George W. Bush that the United States should achieve, within ten years, an electronic medical record for every patient is a significant event. Although it was relatively ignored by the media, it should not go unnoticed by the laboratory industry. (*See sidebar, next page.)*

Feds Will Lead The Way

It means that the federal government will take the leadership role in pushing and tugging the American healthcare system to adopt a universal patient electronic medical record. It also validates a prediction made by THE DARK REPORT almost one year ago.

The primary product produced by every clinical laboratory is information. Thus, anything which changes or improves the way physicians, hospitals, and payers use information will have profound impact on laboratories. What President Bush proposes to be a national goal of this country will radically restructure long-standing relationships between laboratories, physicians, and payers.

For example, the gap in access to lab test data on the same patient's hospital inpatient record and his/her physician office file has allowed many hospital laboratory outreach programs to compete successfully against the Two Blood Brothers. Those hospital labs keep the patient's inpatient test results and outpatient test results in a data base accessible by physicians.

A universal EMR requires that all laboratory data be formatted to populate the patient's primary EMR repository. This eliminates any competitive advantage that once accrued to laboratories capable of giving physicians access to fuller sets of patient test data than a competing laboratory. It is one example of how a universal EMR alters the competitive status quo between laboratories. But the universal EMR may affect the competitive lab marketplace in other ways which may be equally profound.

President Bush Declares 10-Year Goal of Universal EMR: Media Goes "Ho Hum!"

IT WAS AN ANNOUNCEMENT that generated two surprises. First, that President Bush would declare a goal that all patients should have an electronic medical record (EMR) within ten years. Second, that the media would totally ignore this major pronouncement.

President Bush announced this major health initiative on Monday, April 26, 2004. This was during *Executive War College* week. Participants were surprised to find no mention of this announcement in major newspapers such as the *Wall Street Journal* and the *New York Times* in the days which followed the President's remarks. President Bush is urging four steps to accomplish 100% conversion to an electronic patient medical record within ten years.

STEP ONE: is to complete and adopt "standards that will allow medical information to be stored and shared electronically while assuring privacy and security." He noted that the **Department of Health and Human Services** (HSS) has collaborated with other federal agencies and private entities to establish voluntary standards. These efforts are accelerating the use of EMR-compatible standards by federal agencies. Standards are already available for transmitting X-Rays over the Internet, electronically reporting laboratory results and automatically entering the data into a patient's EMR, if it exists, and electronic prescription ordering.

STEP TWO: is to double federal funding of demonstration projects dealing with healthcare information technology. President Bush wants to increase this amount in the next budget. He proposes to spend $100 million during fiscal year (FY) 2005. Funding in this area was $50 million in FY 2004.

STEP THREE: is for the federal government's existing healthcare programs—each a major purchaser of healthcare—to "create incentives and opportunities for healthcare providers to use electronic records." In his announcement, President Bush directed federal agencies such as Medicare, Medicaid, Federal Health Benefits Program, Veteran's administration, and the Department of Defense to propose modifications and new actions and submit these recommendations to his office within 90 days.

STEP FOUR: is the creation of a new government position, the National Health Information Technology Coordinator. This will be a sub-Cabinet level post within HHS. This Coordinator is to guide development work on universal electronic formats in healthcare and guide partnerships "between government agencies and private sector stakeholders to speed the adoption of health information technology."

The following week, on May 6, 2004, HHS announced the new position would be filled by David J. Brailer, M.D., Ph.D., who is currently a senior fellow at **Health Technology Center** in San Francisco, California. Previously he spent a decade as Chairman and CEO of **CareScience Inc.**, a healthcare management company based in Englewood, Colorado.

For these reasons, THE DARK REPORT recommends that laboratory executives and pathologists include this topic in strategic planning efforts undertaken by their laboratory. There is plenty of evidence to support the conclusion that the drive to a universal patient EMR will happen with dramatic speed.

First, the goal of a universal EMR is supported by large corporations, private health insurers, and the federal Medicare and Medicaid programs. If there is any dissent in the goal, it is about the speed with which healthcare providers should be pushed to achieve this outcome. The validity of the goal

itself—that all patients have an electronic medical record in a format that can be universally accessed by any legitimate provider or payer—has no visible opposition.

Second, there is consensus that a universal EMR will improve patient safety and patient outcomes. It is the right thing to do for ethical reasons.

Third, the universal EMR will reduce healthcare costs in a variety of ways. By reducing errors and gaps in care, it lowers the cost per healthcare encounter. Because data can be collected, stored, accessed, analyzed, and shared electronically, administrative costs will decline.

Last year, THE DARK REPORT was first to identify that the federal government will be the primary driver in the move to adopt a universal EMR.

Fourth, the ability to perform clinical research is greatly aided by a universal electronic medical record. It will be possible to identify patients with the ideal characteristics to be part of a clinical study. It will also be feasible to use blind data from large populations of patients and mine that data for patterns that yield clinically-relevant knowledge. Both activities are literally impossible to accomplish in today's healthcare environment.

Last year, THE DARK REPORT was first to identify that the federal government will be the primary driver in the move to adopt a universal EMR. That prediction was made following a day in July 2003 when HHS made two important announcements. One, HHS had licensed SNOMED-CT from the **College of American Pathology** (CAP). The five-year contract will pay CAP $32.4 million and make SNOMED-CT available to any healthcare provider in the United States at no charge.

IOM's Universal EMR Format

The second announcement was that HHS had chartered the **Institute of Medicine** (IOM) to develop a template for the universal medical record. It is to incorporate the HL-7 language. IOM is to make public the product of its work this fall. *(See TDR, July 7, 2003.)*

It is also important to know that the **National Health Service** (NHS) in the United Kingdom is also pursuing the same goal. England is the first country within the U.K. to sign contracts with healthcare IT vendors to accomplish a universal EMR and a central healthcare repository. Lessons learned in both countries will be valuable. THE DARK REPORT is tracking progress in the U.K. through its activities in producing the *Frontiers in Laboratory Management* (FiLM) conference in England each February.

New Lab Winners & Losers

Laboratories, which are primarily information factories, need to track the development of this trend. THE DARK REPORT reiterates its belief that widespread introduction of the universal EMR will trigger radical shifts in longstanding relationships between laboratories, client physicians, and payers.

Among laboratories, there will be new winners and new losers because of this process. The most vulnerable will be small anatomic pathology group practices. By failing to invest in their business capabilities, and by failing to understand the ramifications of the universal EMR to their immediate situation, they will become dinosaurs. Failure to evolve with the new climate will cede the market to those laboratories which do. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Business Week Magazine placed **Bio-Reference Laboratories, Inc.** (BRLI) on its 2004 list of the Top 100 Hot Growth Stocks. BRLI, based in Elmwood Park, New Jersey, was ranked 16th. *Business Week* announced the list in its June 7, 2004 issue. With steady growth in revenues and net profits in recent years, BRLI's shares have performed well for investors.

SALES & MARKETING

• **Lab*One*, Inc.** of Lenaxa, Kansas has a new Executive Vice President of Healthcare Marketing. Philip A. Spencer was promoted to that position last month. Before coming to Lab*One*, Spencer held business development positions at both **Laboratory Corporation of America** and **DIANON Systems, Inc.**

• **NeoGenomics, Inc.**, a public cytogenetics company in Fort Myers, Florida, hired Gary LaBarge to be Area Sales Manager for Southeast Florida. LaBarge had formerly been with **IMPATH, Inc.**, with responsibilities for business in Florida.

MOLECULAR COMPUTER FOR LAB TESTING DEVELOPED IN ISRAEL

Think of an *in vivo* diagnostic instrument that uses RNA to identify disease states in the body—and small enough that one trillion could fit within a water drop! That's the dream of researchers at the **Weizmann Institute of Science** in Rehovot, Israel. In a paper published online in the journal *Nature* on April 28, 2004, Ehud Shapiro, Ph.D. and his colleagues reported on using mRNA to identify the presence of "disease-related genes associated with models of small-cell lung cancer and prostate cancer." The proof of principle was conducted *in vitro*, in a test tube. The "hardware" in the computer is an enzyme which cuts DNA strands in a specific way, yielding a "yes" or "no" answer at the end of the reaction. Researchers state that any practical application of this technology will take many years to achieve.

ARNOLD O. BECKMAN, PHD

One of the giants of the diagnostic testing industry has died at the age of 104. Arnold O. Beckman, Ph.D., died in his sleep on May 18, 2004. He founded **Beckman Instruments** in 1935 to sell his first patented invention, a pH meter. He was Chairman Emeritus at the company, now called **Beckman Coulter Inc.** In 1987, Beckman earned a place in the National Inventors Hall of Hame.

CHROMAVISION

A correction and clarification about **ChromaVision Medical Systems, Inc.**, based in San Juan Capistrano, California. As noted in the last issue of THE DARK REPORT, ChromaVision has raised $26 million in new capital and is refocusing its strategic business plan. It intends to open a laboratory and perform a variety of testing services, including tests using the ChromaVision ACIS® (for automated cellular imaging system). ChromaVision also will continue selling its ACIS instruments to researchers, laboratories and pathology group practices. It has, however, terminated its relationship with **US Labs, Inc.** As part of its new business strategy, the Company has internalized the remote pathology ACCESS support services previously provided by U.S. Labs.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 28, 2004.