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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Laboratory Medicine Goes Global

IN MY OPINION, THE ABILITY OF TWO ST. LOUIS HOSPITALS TO PROVIDE a sophisticated menu of reference testing for a developing nation located more than 12,000 miles away is remarkable. *(See pages 2-6.)* It provides compelling evidence that laboratory medicine is undergoing its own globalization process.

Couple the accomplishment of **Washington University Medical School** and **Barnes-Jewish Hospital** in serving the reference testing needs of Eritrea with the ongoing effort to understand and control the spread of SARS (severe acute respiratory syndrome), and the progress toward an internationalized system of laboratory medicine becomes easier to see.

I think this globalization process is supported by three fundamental developments. The first is overnight package delivery. Since **Federal Express** appeared on the scene in the mid-1980s, the overnight package delivery industry has grown steadily. It is constantly upgrading services, like package tracking capabilities. It is steadily opening new markets and expanding its geographical coverage. As a result, clinical laboratories find it easier and easier to economically serve clients located farther away than in the past.

The second fundamental development is telecommunications, including fax and Internet. There are a few of us still out there who remember when fax machines didn't exist. Introduced in the early 1980s, fax machines have shrunk in size and give anyone with a basic telephone line the ability to send and receive documents, including test requisitions and lab test reports.

The third fundamental development is the ongoing consolidation among diagnostic manufacturers. All through the 1990s, the world's largest diagnostic companies acquired companies and technologies that supported their strategic vision. This business activity crossed international borders and allowed labs almost anywhere in the world to have access to the same diagnostic assays.

Healthcare will always be local. But what is changing is the ability of clinical laboratories to provide the customized services needed by local providers across ever greater distances. Lab directors and pathologists should understand that this trend can be both a threat and an opportunity for their laboratory. TDR

Eritrea Uses St. Louis For Reference Testing

Newly-independent nation relies on laboratories in St. Louis to perform wide range of lab tests

CEO SUMMARY: On one level, it's the classic story of volunteerism and help for a developing nation. But on another level, it's a dramatic demonstration of how new technologies allow two hospital laboratories in St. Louis, Missouri to effectively provide reference laboratory tests and related services to Eritrea, a small country located 12,000 miles from the United States on the Horn of Africa.

By June G. Smart, Ph.D.

SINCE 1996, TWO St. Louis hospital labs have provided reference laboratory testing for physicians in Asmara, Eritrea, halfway around the globe on the Horn of Africa.

This unusual story is a heartwarming example of pathologists and laboratory professionals giving help to a third world country. But there is another, equally interesting, aspect to this story. The weekly reference testing relationship between St. Louis and Asmara demonstrates that clinical laboratories in this country are capable of supporting clinicians anywhere in the world with cost-effective, high-quality laboratory tests.

In St. Louis, laboratories at the **Washington University School of Medicine** (WUSM) and **Barnes-Jewish Hospital** provide reference testing, including hematopathology, for the **Central Health Laboratory** (CHL) in Asmara, the capital city of Eritrea. Champion for this project is Jack Ladenson, Ph.D., Professor of Pathology and Interim Director, Division of Laboratory Medicine at WUSM.

The project is the result of personal relationships and the activities of **Pathologists Overseas**, an organization founded in 1991 by retired pathologist Heinze Hoenecke, M.D. "Dr. Hoenecke's vision was to improve and provide affordable clinical lab and pathology services to underserved areas worldwide," stated Ladenson. "He asked for volunteer pathologists, clinical laboratory scientists, and medical technologists

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to help. His first project was in Kenya, but activities quickly expanded into Eritrea, St. Lucia, Nepal, Madagascar, Samoa and Bhutan."

The Asmara–St. Louis connection resulted from the teamwork of Ladenson and Dr. Cesare Manetti, a volunteer pathologist in Kenya. "Dr. Manetti grew up in Eritrea," recalled Ladenson. "He saw the value of what was done in Kenya and took the idea to Asmara. The project was initiated in 1994.

"I took my first trip in 1996, which was just three years after Eritrea gained its independence after a long civil war," he continued. "During that war, Eritreans had created a laboratory, surgical suites, a pharmacy plant and other health care services. These were located in a set of container cars in caves in Northern Eritrea. The laboratories set up by Melles Seyoum, now director of the Central Health Laboratory, were an amazing achievement!"

Reference Testing Support

"When we visited Eritrea, we thought we could help them, but how?" observed Ladenson. "To determine the testing needs of the population, we worked closely with the Minister of Health and many local physicians. The decision was to support unrestricted ordering of tests that were clinically relevant to the patient's condition, essentially allowing Eritrean physicians the same access to laboratory testing as the physicians at Barnes-Jewish Hospital."

This decision generated a series of tough questions. How would these tests get to St. Louis? What had to happen to guarantee that specimens received in St. Louis were viable for testing?

"Our first mission was to evaluate specimen integrity," said Ladenson. "Mitchell Scott, Ph.D., Professor of Pathology and Co-director of Clinical Chemistry, tackled this effort. He developed a method to test the stability of specimens. We tested samples at the Barnes-Jewish Hospital laboratory in St. Louis. Those specimens were then sent to Eritrea on cold packs via **Federal Express** or **DHL**, where the specimens were unpacked, refrigerated, repacked, and returned to St. Louis for repeat testing.

No Frozen Specimens

"This process allowed us to determine how we could be sure which tests would make the grade," he added. "Planes fly in and out of Asmara only three or four days per week, so we must consider specimen stability from the time drawn to the potential date we will receive the specimen. Also, we cannot ship frozen specimens. It takes two days for the specimens to reach us and the dry ice available in Eritrea is not dense enough to keep specimens frozen over that transit time.

"Once testing activities commenced, we found some interesting ordering patterns," said Ladenson. "We provide unrestricted ordering—so long as the test is stable at 4° C. Any test that is available to a patient at Barnes-Jewish Hospital is available to a patient in Eritrea. However, tests for Eritrean patients that are referred to other labs by Barnes-Jewish Hospital must meet the same specific approval criteria as that used for St. Louis patients.

"Very expensive tests are included, as are tests often misinterpreted, and tests that have value in a highly selected group of patients," he explained. "These types of tests need prior approval by the on-call resident or fellow. Because communication can be difficult, we discourage them from drawing samples until the Central Health Laboratory has consulted us for approval. The highest volume of procedures are thyroid function tests, fertility testing, and lipids. It turns out to be not much different from the

United States, but different from what many had predicted.

"During 1998, the first year of testing, we performed about 2,500 tests. Forty percent were thyroid function (T4, T uptake, TSH), 30% were fertility tests (estradiol, FSH, LH, prolactin and progesterone), along with a few hepatitis B and C antibodies, ANA's and vitamin B12's. Testing increased through 2001 to almost 6,000 specimens and expanded to include, rheumatoid factors, H-pylori IgG, toxoplasma IgG, PSA's, testosterone, creatine kinase total and MB, carbamazepine, and some phenobarbitals.

"In Asmara, the Central Health Lab focuses on what they can do with the equipment they have. They send us those tests that require more expertise," Ladenson noted. "However, I am pleased to say they now do their own lipids and thyroid testing, thanks to **Roche Diagnostics**, which donated a refurbished Hitachi 717. We don't do much infectious disease testing like HIV for them because that is supported in Asmara by a variety of grants."

Problem-Solving Skills

"When working in a lab in a developing country, it makes you think outside of the box," mused Ladenson. "You have to resolve issues that never come up in the United States. You develop new ways of solving problems. It is challenging and fun at the same time. It occasionally helps if you are a dinosaur of lab medicine, as you can remember the 'old testing' methodologies.

"For patients not living in Asmara, seven regional hospitals have been established around Eritrea. These seven regional hospital labs do basic chemistry and CBC's. They utilize small chemistry analyzers made in India which are similar to physician office testing analyzers, but on a smaller scale. CBC's are done on small cell counters donated by **Beckman Coulter International**. The equipment in the regional hospital labs is corelated with the equipment in the Central Health Lab, which is correlated with equipment in St. Louis," said Ladenson.

"Numerous companies have donated laboratory equipment for Eritrea. In many cases, these companies followed through to insure the equipment is functional," noted Ladenson. "Companies

Other Hospital Labs Can Offer Similar Help

"I BELIEVE MOST LARGE HOSPITALS or medical centers could provide similar reference testing services to developing countries, once the logistics are established," said Jack Ladenson, Ph.D. "But there must be a champion for the program; otherwise it's forgotten.

"One reward from this program is that our laboratory staff get a sense of volunteerism by working on these specimens," observed Ladenson, who is Interim Director, Division of Laboratory Medicine at Washington University School of Medicine in St. Louis, Missouri. "Most of our people have never been to Eritrea as a volunteer. Yet they get a great deal of satisfaction from providing patient care across such a long distance.

"Also, by working on these specimens, we get to see diseases that are usually only textbook cases in the United States," he added. "I am regularly asked by the staff to give lectures on the cases that we see and about the project in general.

"Another way this trans-global project has benefited our daily lab operation is because our laboratory staff has gained a keener understanding about the importance of specimen identification and specimen handling. There is more attention to detail. This pays off with all specimens that we receive in the lab, regardless of whether they come from inside our hospital or halfway around the world from Eritrea."

that donated equipment or supplies are **Becton Dickinson Vacutainer Systems**, C**omp Pro Med. Inc.**, Roche Diagnostics Corporation, **Dade Behring, Inc**, **Medical Analysis Systems Inc.**, **Life Scan**, **Mallinckrodt, Inc.**, and **Radiometer**. We've also received support from a grant from the United States **Agency for International Development** (AID).

Solving Problems

"We addressed problems with inventory control and the severe shortage of personnel. We developed a system whereby the slope and intercepts are set so results match both the Hitachi in Asmara and the Hitachi in St. Louis. This gives us a reliable way to cross check and confirm that results are within the defined parameters. It also allows us to utilize the same reagents in both the regional hospitals and the Central Health Laboratory," stated Ladenson.

"Use of the same reagents and supplies makes training and inventory control easier," he explained. "We find no evidence to suggest that, because of different equipment using the same reagents, testing is compromised in any way. Now we are in the process of working on quality control and patient comparisons."

Ladenson discussed results reporting. "Once tests are completed in St. Louis, we need to transmit the results. This is not as simple as in the United States. In developing countries, electronic messaging is not as sophisticated as here. We use fax more than e-mail. That's because we can't be sure if they received the e-mail. The fax has proved to be more reliable. There is always the phone, but that can become expensive."

Cost-consciousness is part of the program. "In total, the program costs us between $60,000 and $70,000 per year," estimated Ladenson. "About one-third of that is shipping costs. This is a real bargain because it provides care to about four million people."

One interesting aspect of the testing relationship has been the lack of a language barrier. "From our lab, Mitchell Scott has visited Eritria and knows the personnel in the Central Health Laboratory. He has met the two full time Pathologists Overseas volunteers at the Central Lab in Asmara," he said. "Their names are Gwen Williams and Susan Morin (in Eritrea for one and three years, respectively). Both are medical technologists from the U.S., with previous experience in the Peace Corps. There is no language barrier for the volunteers, as English is used for teaching all courses after fifth grade in Eritrea."

Ladenson provided details about the volunteer process. "We have learned that it is best that people be willing to spend at least six months on these projects," he noted. "It provides continuity and allows more to be accomplished.

"Currently we are looking for a clinical microbiologist for at least six months of service. This is a great opportunity for the right person to provide their expertise and knowledge to some Eritreans who are very dedicated to laboratory medicine," enthused Ladenson.

Little Support Infrastructure

"Things we take for granted in American hospitals do not exist in developing countries like Eritrea," he noted. "There are no professional bodies that you can call to help with a problem. There are no other consulting pathologists with whom you can discuss your difficult case. There is no real infrastructure for laboratory services like we have here.

"As a result, not only do we provide reference testing, but they use us as a conduit for information. We help with education, consultation, and a variety of things to make them part of our laboratory organization here in St. Louis.

"That said, they set their priorities as to how we can assist," said Ladenson.

"We always want to work within their range of needs and capabilities. Transplanted technology does not always work. It is important to take time and understand problems unique to their situation. We tend to suggest ways that we can support them and not impose what we think should be done."

Ladenson's enthusiasm for the St. Louis–Asmara reference testing relationship is obvious. "I would love to share with others how to set up this type of program. Flexibility, patience, commitment, a clear set of objectives, and a cultural awareness are most important," he noted.

"There should be a personal or collegial relationship with someone in the chosen location," continued Ladenson. "That means there is a champion on both sides of the equation. The shipping of specimens, calibration of instruments, consistency of reagents, and many of the clinical aspects of running a laboratory all come into play. Be prepared for delays, setbacks and some frustration, but the rewards are tremendous as you see how such testing benefits patients."

Doing It Differently

If Ladenson were starting a new reference testing project with another location in the world, he would do a few things differently. "First, we would establish a sample identification system that is more rigid and very specific," he said. "In Eritrea, people go by one name, not two as we do. They also don't have unique identifiers, like a social security number. Many don't know their birth date. With experience, we've 'lightened up' on accepting the same specimen identification criteria for Eritrea that we have in the U.S. Obviously we clarify as much as possible.

"Also, having a computer from day one would help avoid handwritten communications for test lists and other important information about specimens," advised Ladenson. "It would make it easier to confirm, by e-mail, the shipment and receipt of specimens."

Not surprisingly, the laboratory staff at WUSM and Barnes-Jewish Hospital often wonder what happens to the patients in Eritrea. "If an individual is diagnosed with a disease that's untreatable in Eritrea, one of several things may happen," stated Ladenson. "Some individuals seek treatment outside the country. Some receive donations of medical therapy from health facilities in various countries. For example, a number of children with leukemia have been treated in Germany at no charge.

Patients Are Grateful

"Even when treatment may not be possible, many Eritrean patients still express gratitude," he continued. "Because they understand what is wrong with them, they can better prepare for the future."

THE DARK REPORT observes that, as baby-boomer medical technologists retire, the number of volunteers for these types of international projects will probably increase. Visit Pathologists Overseas, Inc. at *http://members.aol.com/pathoverc/-home.html* for more information.

For laboratory directors and pathologists, the Asmara–St. Louis reference testing relationship is a powerful demonstration of how rapidly the world is shrinking. It is a reminder that laboratories must think globally, even as they act locally, because the ability of distant laboratories to offer services in any region is becoming easier and easier to do well. In coming years, local competition may come from distant laboratory competitors. TDR

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Laboratory Management Update

Beaumont Reference Labs Earns ISO-9000 for Outreach

By Kip Carpenter

MOTIVATED BY THE GOAL of improving all aspects of its laboratory outreach program, **Beaumont Reference Laboratories** (BRL) of Royal Oaks, Michigan recently earned its ISO-9000:2001 certification.

"In the competitive market for lab testing, we wanted to raise the bar," stated Joseph E. Skrisson, Director of Business Development and Operations at BRL. "We believed ISO-9000 was an effective way to instill a quality culture in all aspects of our laboratory outreach business.

The interesting twist on this story is why BRL's leadership team introduced ISO-9000 only to the outreach portion of its lab. "Inpatient laboratory activities are well-covered by existing accreditation programs, like CAP (**College of American Pathologists**)," noted Skrisson. "But when it comes to outreach, we felt there is no comparable emphasis.

Strategic Decision

"Yet laboratory outreach programs are complex businesses," he explained. "We have 304 employees responsible for such functions as courier services, processing, client services, billing, support for electronic ordering and resulting for physician office clients, marketing, and sales.

"From a strategic perspective, we decided it was time to stop reacting to those daily problems common to all laboratories," he explained. "Our goal was to develop work processes that prevent problems and help us continuously improve the quality of our services."

Skrisson and his administrative team recognized that, since few people working in medical laboratories have been exposed to formal training in quality process improvement programs, BRL faced two business challenges. First, it needed to embrace a proven quality management system. Second, it would make it easier to train laboratory staff if this quality management system came with a well-established program of education.

Competitive Marketing Edge

"We opted for ISO-9000 because it met both of these criteria, plus it offered us another benefit," observed Skrisson. "Because of the auto companies and the heavy manufacturing base in Michigan, payers and patients view ISO-9000 certification as a sign of higher quality. As Michigan's first ISO-certified clinical laboratory, BRL gains an advantage in our marketing efforts."

Employee reaction to the management methods of ISO-9000 was surprisingly postive. "In normal times, many people in the laboratory feel invisible," noted Skrisson. "ISO certification motivated our team and gave it a measurable goal with high visibility within our parent health system. At the same time, ISO-9000 instilled a quality culture in our outreach activities and is proving to be a platform for productivity gains that we expect to sustain over many years."

ISO-9000 is famous for requiring documentation, but that didn't prove to be a burden at BRL. "As a fast-growing laboratory, there were many activities

which lacked written procedures and documentation," Skrisson said. "In our lab, we found it useful to go through the steps needed to evaluate work processes and create the documentation to support them. It's helped reduce variability and differences in how various people do the same task."

Solving Problems

One result of the ISO certification effort is a change in how management and lab staff view daily work flow. "ISO places major emphasis on identifying repetitive problems, then putting solutions in place which prevent those problems from happening," explained Skrisson.

"I think that this is unique and new for most clinical laboratories," he added. "As an industry, we're great at responding to issues. We're great at QA/QC. But we're not good at looking at how to design our work processes with an eye to preventing problems.

"ISO encourages our people to work in teams and look for process improvements in their operations," Skrisson said. "It gives them the knowledge and the tools to identify and implement solutions, then move on to find other problems that can be eliminated by redesigning the appropriate work processes. In fact, ISO forces you to constantly look at what you're doing, make improvements, and immediately move on to the next improvement opportunity."

Enthusiastic Support

Within the BRL outreach program, staff support has been enthusiastic. "There's enthusiasm because employees see problems that they spent time on each day getting permanently fixed! And they realize there's an important difference from the past. Because the system itself is fixed, they have treated the root cause and not the symptoms."

Skrisson offers a few management lessons for lab directors and pathologists considering ISO-9000 or similar types of quality management systems. "First, it was not expensive for us to implement ISO-9000 and become certified," he offered. "Out-of-pocket, we spent about $50,000 on implementation and registration and another $50,000 for consulting services. We also incurred staff time in training and similar types of expenses. In most cases, improvements in quality and productivity traced back to these programs means that payback is speedy.

"Second, at BRL, we tackled three other projects at the same time," Skrisson said. "This included moving our laboratory to a new five-story building and bringing up major automated systems. We are proud of our accomplishments, but normally an ISO implementation can be in 12 to 18 months. It took us approximately 23 months.

Experienced Consultants

"I recommend that ISO certification should be done as the major management initiative," he continued. "Also, should you want to use a consultant, find one with experience implementing ISO-9000 in a clinical laboratory. In our case, less time would have been spent in translating our existing laboratory documents into ISO documents if our ISO consultants were experienced in clinical laboratory operations."

THE DARK REPORT observes that Beaumont Reference Laboratories pursued ISO-9000 certification because it wanted to become more competitive—while boosting quality and increasing productivity. BRL is another example of an early-adopter laboratory embracing a management philosophy of continuous improvement. "That's certainly true," said Skrisson. "It's becoming a way of life around here. People like having the knowledge, the power, and the support to fix problems throughout our laboratory organization. **TDR**

Contact Joe Skrisson at 248-551-5017.

Laboratories Responding to Changes

Nine Key Trends Are Shaping Nation's Healthcare Informatics

CEO SUMMARY: During the 1990s, hospital spending on information technology was devoted primarily to acquiring upgraded versions of software systems for clinical services such as laboratory, pharmacy, and radiology. That's no longer true. As the following nine key trends in healthcare informatics demonstrate, hospitals, physicians, and other types of healthcare providers are moving aggressively to acquire and deploy a surprisingly wide range of IT solutions. From wireless to handhelds, clinical laboratories will be challenged to maintain the ability to connect and feed laboratory test data into these new informatics channels.

HEALTHCARE INFORMATICS continues to evolve at a rapid pace. Each generation of software and hardware technology provides clinical laboratories with capabilities and opportunities to further enhance the contribution of laboratory medicine.

Because laboratories are essentially information factories, these swift changes in information technologies (IT) can have huge impact on both labs and the end users of the laboratory test data they generate.

To help lab directors and pathologists stay informed about these important developments, THE DARK REPORT provides this briefing about nine major trends in healthcare IT recently identified by the editors of *Healthcare Informatics*, a publication widely-read by hospital CIOs. These nine trends represent informatics initiatives now occurring in the nation's leading hospitals, physicians' offices, and other types of providers.

Nine healthcare IT trends were identified, based on four criteria. Technologies needed: 1) to support improved efficiencies in the delivery of healthcare services; 2) to be compatible with HIPAA compliance; 3) to be effective in use; 4) and to have mature products established and working successfully in the healthcare marketplace. Of equal importance, these nine trends reflect demand within the hospital industry and vendor's market responses to fill that demand.

Health Informatics Trend #1
• BIOMETRICS •

CONTROLLING ACCESS to information systems and confirming the identity of users is a high-priority task as the healthcare industry struggles to comply with HIPAA.

Biometrics links some form of access control to a human attribute, something which can't be lost, stolen, or duplicated. Fingerprints and retinal scans are the most familiar forms of biometric access controls.

In the 36-month period from 2002 through 2004, annual spending on biometric systems will increase from $110 million to $302 million, according to a report issued last fall by **Allied Business Intelligence**, located in Oyster Bay, New York.

One pilot project in retinal scan biometrics is now taking shape at the **University of South Alabama Hospitals**, a three-hospital system in Mobile, Alabama. **Blue Cross Blue Shield of Rhode Island** is implementing an integrated system that integrates a fingerprint sensor with the company's internal network.

Health Informatics Trend #2
• COMPUTERIZED PHYSICIAN ORDER ENTRY (CPOE) •

RECOGNIZED AS ONE of the fast-growing product segments in healthcare IT, computerized physician order entry (CPOE) is widely viewed as a way to reduce medical errors and improve patient safety.

CPOE is one of the first three standards selected by the **Leapfrog Group** to measure patient safety across different hospitals. In a 2002 poll of 517 hospitals, the Leapfrog Group reported that 25% intended to implement a CPOE system by 2004.

The new generation of CPOE products incorporate capabilities such as clinical decision support tools, alerts, clinical pathways, and ordering rules. These complement and support the basic function of computer order entry for pharmacy, lab, radiology, and other services. It is recognized that the best performance of CPOE comes when it is integrated with an electronic medical records (EMR) system.

CPOE is still in its earliest stages. Products are not yet robust. Early adopters tend to be inpatient settings, par-

ticularly in academic medical centers. **Vanderbilt University Medical Center** developed a home-grown CPOE, called "WizOrder." It is designed to reduce variation in how healthcare is delivered. Among other benefits, it is reducing laboratory test utilization by as much as 40% in individual departments. **McKesson Corp.** licensed this product and now markets under the name Expert Orders™.

Health Informatics Trend #3
• DISEASE MANAGEMENT •

DISEASE MANAGEMENT PROGRAMS should be on every hospital CEO's strategic radar screen. It is a fast-growing trend, fueled by employers' interest in controlling healthcare costs.

The scale of this surging interest is revealed in statistics released by **Hewitt Associates**, the large human resources consulting firm. Last fall, Hewitt announced that, in just five years, the number of large corporations supporting disease management programs had doubled, from 9.5% in 1997 to over 19%. It predicted that, by year's end 2003, 30% of the nation's large corporations would have disease management programs in place.

Most of these programs are administered through insurance plans and concentrate on the three major chronic diseases: congestive heart failure, diabetes, and asthma. In 2002, it is estimated that $580 million was spent on disease management programs in the United States.

In these programs, nurses contact patients and provide support and information. In contacting patients, nurses are supported with IT-based capabilities for electronic communication between patients and providers. Features such as automation of home care monitoring and the ability to mine clinical data repositories are also on the "want list" of disease management programs.

Health Informatics Trend #4
• HANDHELD DEVICES •

IT IS BECOMING INCREASINGLY COMMON to see a physician, nurse, or healthcare worker using a PDA (personal display appliance) or tablet computer. Early users are enthusiastic supporters of the concept.

The growth of this trend will be in tandem with the installation of wireless networks. *(See "Wireless", page 9.)* Already experts agree that a "strong plurality of hospital-based organizations nationwide are at some stage of handheld development.

Handheld devices represent the intersection of efforts to enable CPOE, reduce prescription errors, allow access to clinical data such as lab test results, checking patient wristband bar codes for positive identity verification, and a host of other uses. The arrival of handheld PDAs with color screens will accelerate this process, since many clinical applications use color to flag important information.

One early adopter is 508-bed **Abington Hospital** in Abington, Pennsylvania. For the past two years, it has operated an 802.11b wireless local wide area network that links 60 mobile wireless workstations. These, along with another 300 stationary wireless workstations, are connected with the hospital's EMR.

And, surely a sign that the "handheld" era has arrived is news that the **University of Louisville School of Medicine** is distributing handhelds to each of its 600 undergraduate medical students. It is first medical school in the nation to do this. Among the medical students, a common use of the

handhelds is to use them for reference access to the PDR and **Lippencott Williams & Wilkins Publishers'** "Five Minute Clinical Consult."

Health Informatics Trend #5
• NATIONAL CONNECTIVITY •

REMEMBER CHINS–Community Health Information Networks? These were regional healthcare data repositories much discussed in the early 1990s, but which failed to become a reality.

The need to share healthcare data never diminished. What rendered the CHIN concept obsolete was the development of the Web, along with enabling hardware and software.

In the private hospital sector, projects like the **Winona Health Project** in Winona, Minnesota and **Healthbridge** (pooling clinical data from 25 regional hospitals) in Cincinnati, Ohio have attracted national attention. Both are pioneering attempts to connect hospitals, physicians, patients, and payers in some type of network arrangement.

Further impetus to electronically connect healthcare centers has come from various levels of government following the 9/11 terrorist attacks and the anthrax attacks a month later. Federal money is now funding projects to link public health agencies and laboratories as a phase one, with further connections to hospitals as a subsequent goal.

The benefits can be substantial. In Vermont, THE DARK REPORT is tracking a statewide collaboration involving all the state's hospital laboratories. They've connected their lab test data repositories and normalized test results across all sites. Through data mining, it is now possible to identify undiagnosed adult-onset diabetics by comparing the multi-year test results of a single patient's HbA1c testing. Much of the funding to establish the connections between these hospital labs came from a federal **NIH** grant administered through the **Vermont Department of Health**.

Health Informatics Trend #6
• STORAGE •

IF BRUCE A. FRIEDMAN, M.D. IS RIGHT, the healthcare system will be overwhelmed by the sheer volume of clinical data generated from genetic, proteomic, and molecular-level healthcare technologies.

Dr. Friedman is Director of Ancillary Information Systems at the **University of Michigan Health System** in Ann Arbor, Michigan. His area of informatics expertise is clinical laboratory and pathology.

"Laboratory directors should consider how the impact of three converging trends will affect laboratory operations," he said. "First, about 70% of a patient's medical record retained over time is comprised of laboratory test data. Second, newer generations of lab testing produce proportionately huge amounts of data. Third, radiology, as it digitizes images, is generating significant volumes of data."

Dr. Friedman rightly identifies the coming "storage crunch" facing hospitals and health systems. One expert says that the volume of reference data requiring storage is increasing 70% per year!

"We see that any hospital of a decent size may generate between 10 and 12 terabytes of information annually," observed Robert Burgess, Senior Manager at **First Consulting Group** in Long Beach, California. A terabyte is 1,024 gigabytes.

Healthcare Informatics identifies five technologies as crucial in creating the capability to store and access clin-

Nine Trends Shaping Health IT

THESE NINE TRENDS are driving changes to healthcare informatics in hospitals and physicians' offices.

1. **Biometrics:** Using unique human attributes to allow access to a secure system.
2. **CPOE:** Computerized physician order entry viewed as a way to improve patient safety, raise healthcare outcomes, better control costs.
3. **Disease Management:** Corporate America's solution to controlling the cost of healthcare while improving outcomes.
4. **Handhelds:** Tablet computers and PDAs (personal display appliances) fast-becoming a favorite among physicians, nurses, and hospital staff.
5. **National Connectivity:** Need to exchange data continues to drive private efforts to link providers and payers. Government response to 9/11 and anthrax attacks generates money to link public health resources.
6. **Storage:** Watch out! Exponentially-growing volumes of healthcare data will tax the capacity of health system IT departments.
7. **Transaction Processing:** Nationwide push to speed up payments and reduce administrative costs complements HIPAA requirements for standardized formats.
8. **Web Services:** Consensus is that the Web provides a better and faster way to integrate new IT services.
9. **Wireless:** Convenience of cell phones comes to a multitude of healthcare services and tasks—while maintaining continuous contact with the host computer.

ical data. Hospitals are actively moving to acquire them:

1) disk arrays, computers optimized for single-purpose storage. Each can cost $1 million and hold 30 terabytes of data.

2) Network-attached storage (NAS), which attaches disk arrays to computers throughout departments.

3) Storage area network, lays on top of an NAS and uses fiber channel to create communications bandwidths of one to two gigabytes.

4) Storage virtualization, capable of pooling data across widely-dispersed storage devices and even across multiple computing platforms and different types of storage media.

5) Storage management software, the prime tool for coping with huge quantities of data. Predictions are that up to 80% of the cost of new data repositories will be spent on storage management software.

Health Informatics Trend #7
• TRANSACTION PROCESSING •

ONE FREQUENTLY-OVERLOOKED ASPECT of HIPAA is its mandate that clinical transactions, claims, and other administrative functions move toward standardized formats.

This will accelerate efforts by payers and providers to improve transaction processing. The goal is to reduce costs and speed payment of claims. **Gartner Group**, of Stamford, Connecticut, aptly describes the existing gap between reality and ideal. In a study released last fall, Gartner says that, of the $1 trillion spent on healthcare in 2000, about $250 million went to administration. At the same time, 80% of the nation's hospitals had yet to even test whether their network can handle basic electronic transactions!

Despite the recent, and well-publicized, failure of **MedUnite** to establish an economically-sustainable Web-based transaction clearinghouse of large scale, a number of regional efforts have made substantial progress. In Buffalo, New York, four providers and three major insurers launched **WYNHealthENet** in 2001. From a first effort in 1994, the **Utah Health Information Network** (UHIN) has enrolled nearly every payer and provider in the state.

Health Informatics Trend #8
• WEB SERVICES •

GONE ARE THE MUCH-HYPED consumer health Web portals of the late 1990s. The Web is now a serious tool for enabling all types of business and service transactions.

The operative word is "integration." **Accenture** Partner James Hall of London, England says CIOs tell him that 40% of the cost to deploy a new application is spent to connect it to existing applications.

The Web is now used by hospitals to help with internal integration. Outside the hospital environment, the architecture of healthcare enterprise-to-enterprise Web services needs further development, particularly the interoperability glitches between Java and **Microsoft's** .NET.

Another issue is legacy software used by hospitals, physician groups, and payers. Because much legacy software has yet be upgraded as fully Web-enabled, it requires considerable time and expense to program workable solutions. However, informatics experts now consider the Web to be the future of healthcare informatics. In response, both vendors and providers have aligned their strategies to maximize compatibility with the Web.

Health Informatics Trend #9
• WIRELESS •

WIRELESS IS ANOTHER AREA of healthcare informatics where consensus exists across the entire spectrum of healthcare. Vendors report rapid growth in wireless system sales to healthcare entities.

"Probably 25% to 30% of hospitals have fairly large-scale wireless implementations under way now," stated Bruce Kantelis, Vice President, Mobile Computing at McKesson Corporation. "Another significant percentage have spot applications already installed."

Wireless is already supporting a wide range of mobile devices in hospital settings. But experts recommend that hospitals establish an overall wireless strategy first, to help insure that all wireless devices subsequently purchased are compatible with the overall goals of the hospital.

Erie County Medical Center (ECMC) in Buffalo, New York developed its wireless strategy first. Only then did it install a backbone wireless system from **Cisco Systems**. It next took a unique approach to purchasing its wireless devices.

ECMC created a multidisciplinary team of IT and clinical leaders to lead the wireless installation. This team then held "internal hardware fairs." Vendors were invited to show their wares. Physicians, nurses, and other staff members could test and manipulate the devices themselves. Staff preference guided the final mix of wireless devices that were purchased.

Laboratory executives and pathologists who want to see *Healthcare Informatics'* complete description of these trends can find this information at *http://www.healthcare-informatics.-com/issues/2003/02_03/feb.htm.* TDR

SARS Update

SARS Contained in Toronto, Labs Still in Caution Mode

Labs anticipate permanent changes in response to lessons learned from SARS outbreak

IN RECENT DAYS, public health officials in the Canadian province of Ontario have declared the SARS outbreak to be contained.

As described in the last issue of THE DARK REPORT, the outbreak of SARS in Ontario had a significant operational impact on clinical laboratories in the province. *(See TDR, April 14, 2003.)* Both hospital labs and commercial labs were forced to change operations in several ways.

Labs Maintain Vigilence

"Though the SARS outbreak seems to have peaked, our lab has not relaxed any of the procedures we implemented in response to SARS," stated Pat Everitt, Director, Government Relations and External Communications at **MDS Diagnostic Services.** "In fact, the lessons learned from the SARS outbreak will lead to permanent changes.

"For one thing, healthcare officials now use the term 'new normal' to describe operational procedures which will become the norm as a way to protect healthcare workers when treating patients suspected of having SARS," she added. "For labs, the SARS outbreak reinforced the need for continued strict adherence to the lab procedures we've known about for years: proper use of universal precautions, good lab practice and safe transportation techniques. The sudden appearance of a new infectious disease reminds us of their importance."

"It's still early to assess the lessons and changes to laboratory practices which are a result of the SARS experience," stated Ene Underwood. "The number one issue for our staff has been concerns about personal safety. This outbreak powerfully focused our lab organization to ensure that staff understands and has the tools they need to follow standard precautions for handling bodily substances, any of which could potentially contain infectious agents."

Underwood is President and CEO of **Toronto Medical Laboratories**, the 50/50 joint venture between **University Health Network** (which owns three hospitals) and **MDS Inc.** "Even as the SARS outbreak eases in Toronto, there are still patient and staff entrances into the hospitals. Also, visits by vendors to our labs must be arranged in advance," she said.

Source Of Specimens

Underwood's laboratory is collaborating in two separate projects to develop diagnostic tests for SARS. "The declining number of SARS patients reduces the number of control specimens we can collect for these projects," she explained. "It highlights one of the challenges facing researchers developing such tests." TDR

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Lab Industry Briefs

SPECIALTY LABORATORIES RESTORING STABILITY IN SPECIMEN VOLUME

IT'S NO SURPRISE THAT COMPETITORS of **Specialty Laboratories, Inc.** have been willing to spread a variety of rumors about the laboratory company, given its well-publicized troubles with government regulators last year.

Notwithstanding these rumors, the reality at Specialty Labs is quite different. On April 24, the company, based in Santa Monica, California, released its operating results for the first quarter. There was some surprising news for those who believed the company was experiencing ongoing erosion among its customer base.

For second quarter, patient accessions totaled 616,000. Although this was lower than the 830,000 patient accessions for first quarter 2002, it was essentially level with fourth quarter's 614,000 accessions. It is a credible sign that Specialty's existing customers are willing to work through the company's organizational and philosophical restructuring.

This is a particularly strong showing because of long-awaited changes at **Unilab Corporation**, which was once Specialty's largest single client. During first quarter, **Quest Diagnostics Incorporated** completed its acquisition of Unilab and begin to shift reference work away from Specialty Labs. For Specialty to have maintained patient accessions at the same level as the previous quarter, it had to generate more specimens from existing accounts as well as gain new clients.

Revenue for first quarter was $30.3 million, compared to $43.6 million in first quarter 2002. Specialty posted a $2.4 million loss, compared to a $1.6 million profit the previous first quarter.

Frequently, companies which undergo a business crisis emerge from the turmoil leaner, better organized, and with intense focus. Although it is too early to make this conclusion about Specialty Laboratories, its public face is energized and enthusiastic.

There's a similar case of enthusiasm within the hospital marketing division at Quest Diagnostics. That's because executives from the **American Medical Laboratories** acquisition are taking a lead role in driving Quest's sales and marketing to hospitals. During the balance of 2003, expect competition for hospital send-out testing to heat up.

IMPATH BEGINS WORKING ITS WAY THROUGH MAJOR CORPORATE MAKE-OVER

EVEN AS SPECIALTY LABORATORIES, INC. recasts its corporate operations, a similar endeavor is under way at **IMPATH, Inc.**, the sole remaining public company that is organized to offer anatomic pathology services nationally.

IMPATH would like to characterize its internal reorganization in a favorable light, but the reality is somewhat different. Its corporate culture, responsible for impressive growth in specimen volume, revenues, and net profits throughout the 1990's, had a number of weak spots. These finally surfaced over the past year.

One weak spot proved to be IMPATH's CEO. Following an internal audit which uncovered various improprieties, IMPATH's board removed Anu Said, Ph.D., the company's long-time

Chairman and CEO. IMPATH offered few specifics about the problems, other than the departing CEO would repay the company $250,000 in a matter characterized as a "lapse of corporate integrity." *(See TDR, February 10, 2003.)*

Since the arrival of its new Chairman and CEO, Carter H. Eckert, IMPATH has embarked on a wide range of internal initiatives. It has closed a laboratory facility in Southern California, reduced its FTEs by 12%, and slashed capital spending.

Billing and collections is proving to be the company's Achilles' heel. It has already experienced considerable criticism by the investment community over the way it has reported revenue, accounts receivables, and bad debt. In response to that, and for other reasons, IMPATH shifted its accounting to a different method, effective January 1, 2002.

With an underperforming billing and collections department, the company is in a cash squeeze. It only has $1 million in cash on its balance sheet dated 3/31/03. In comparison, at the end of fourth quarter 2002, its cash totaled $5.8 million.

For first quarter, IMPATH reported accounts receivable of $69 million (against 2002 annual revenues of $191 million. Its DSO (days sales outstanding) was 154, an increase from 134 in fourth quarter 2002. To help improve this situation, the company is in the midst of installing a new laboratory information system and billing program.

The anatomic pathology marketplace has seen rapid changes. During the past 12 months, **DIANON Systems** was acquired by **Laboratory Corporation of America**, **AmeriPath** was acquired by **Welsh, Carson, Anderson, & Stowe** and taken private, and IMPATH is sidetracked with internal problems. These developments demonstrate how rapidly the competitive marketplace can change.

Hospital-based pathology groups have a window of opportunity to market their services to office-based physicians. With the national anatomic pathology companies distracted with internal management priorities, they will tend to put less attention and resources into their sales and marketing programs.

DIAGNOSTIC TESTS FOR SARS HEADING INTO THE MARKET

THERE'S A RACE TO BRING the first effective diagnostic test for the SARS virus to market. Development work is taking place at several diagnostic companies around the world.

Last week **Roche Holding AG** announced that it expected to launch a diagnostic test for the SARS virus by late July this year. Roche disclosed that the test would incorporate its PCR technology. It has been collecting specimens from SARS patients in Singapore, Hong Kong, and Malaysia to help in the development of its test.

Just a week earlier, microbiologists at the **University of Hong Kong** announced the development of a non-invasive diagnostic test for the SARS virus. It detects the presence of the coronavirus in nasal swabs or throat cultures. It looks for the RNA of the SARS virus.

Public health authorities are hopeful that an effective laboratory test for detecting the SARS virus can be developed and validated rapidly. The first tests developed to detect SARS are "home brew" and are not automated.

Abbott Laboratories has formed a consortium with **Celera Diagnostics** to develop a SARS tests. Unlike Roche, Abbott has not provided details about its project, nor an estimated date when it believes its test will be ready for widespread clinical use. **TDR**

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

There are rumors coming from the West Coast that government laboratory regulators are targeting at least one laboratory company for some significant violations. Because allegations of compliance violations by the government can severely damage a lab company's reputation, there is a tight lid on information by all parties privy to this story.

ADD TO: Lab regulators

If this story is true, it would fulfill a prediction made last year by THE DARK REPORT. During the time when **Specialty Laboratories, Inc.** was working to resolve its regulatory problems, THE DARK REPORT noted that lab regulators in California have a pattern of major enforcement actions against prominent lab companies and, as a result, would be motivated to look deeper for violations in other lab companies operating in the Golden State.

RESEARCHERS FIND CANCER-RESISTANT STRAIN OF MICE

In what may be a fortuitous piece of luck, cancer researchers discovered a single mouse that was resistant to cancer and have bred offspring that show a genetic resistance to cancer. The work was done at **Wake Forest University Baptist Medical Center** in Winston-Salem, North Carolina. In a study published in the *Proceedings of the National Academy of Scien-ces*, Dr. Zheng Cui reported that mice were injected with a particularly aggressive tumor cell. But one mouse, despite repeated injections, never contracted cancer. The other mice in the study developed cancer and died. After breeding the surviving mouse, researchers found about half the offspring showed cancer resistance. They believe this shows the genetic trait is dominant and likely due to one gene.

MORE ON: genetic cancer resistance

These research findings demonstrate how genetic-based technology is opening up new understanding about the mechanisms of diseases like cancer. Research into gene-based resistance is another example of why molecular diagnostics will play a greater role in a variety of clinical applications.

CAREER MOVES

There's a new lab entrepreneur and a new lab CEO.

- **Sterling Reference Laboratories** in Tacoma, Washington is the new name for a lab company involving Evans Calas, its new CEO. Calas, a long-time lab executive in Puget Sound, managed laboratories in the area for **International Clinical Labs** (ICL), **National Health Laboratories**, and, most recently was with **Dynacare** and **Laboratory Corporation of America**.

- **Alfigen, Inc.**, the specialty cytogenetic testing company based in Pasadena, California, announced that R. Jeffery Lanzalotta has accepted the position of Chief Executive Officer. Lanzalotta was part of the executive team at **Unilab Corporation**, up through its acquisition by **Quest Diagnostics Incorporated** in recent months.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, May 26, 2003

UPCOMING...

- ***Inside News and Emerging LabTrends Revealed at This Year's EXECUTIVE WAR COLLEGE.***
- ***Pathology Practice Conundrum: Win-Win Ways to Structure the New Partner's Buy-In.***
- ***Early Look at the CDC's Views about Patient Safety in Clinical Laboratories.***

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