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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Primum non nocere, or: First, Do No Harm!

"FIRST, DO NO HARM!" IS KNOWN TO EVERY HEALTHCARE PROFESSIONAL. However, I was surprised to learn that this famous phrase is *not* from the Hippocratic Oath!

In checking *wikipedia.com* as I wrote the headline above, I learned that "the phrase expresses one of the principal precepts all medical students are taught in medical school and is a fundamental principle for the emergency medical services." Wikipedia has an interesting discussion of early references to this sentence and its use in medicine, but does note that, by around 1900, it was in common use within the medical community here in the United States.

I wanted to call your attention to this precept of "First, do no harm!" in the context of the disclosure by **Quest Diagnostics Incorporated** that it had, for 18 months during 2007 and 2008, reported inaccurate Vitamin 25(OH) D results to tens of thousands of patients and had instituted a voluntary notification and retest program for patients who had received inaccurate test results. In speaking to THE DARK REPORT (which was first to break this important story) and the national press, Quest Diagnostics is downplaying the potential negative consequences to patients. One Quest pathologist even told a reporter that he doubted that patients would have suffered any harm from the problem! A written Quest statement read on a television news broadcast declared that, following its notification campaign, "we have not been made aware of any adverse impact to patients."

I personally find this a disappointing public face to the problems created by the inaccurate test results Quest Diagnostics sent to patients and their physicians. The *New York Times* reporter quoted one doctor who said, "There was a patient we put on vitamin D and all of a sudden, for the first time ever, the patient came back with what seemed to be a toxic level of vitamin D." When the patient had his Vitamin D tested by another laboratory, the "value was considerably lower." On disease-specific bulletin boards and discussion groups, it is not difficult to find postings dating back two years by concerned patients who are upset by odd or discordant values on their Vitamin D tests performed by Quest.

By repeatedly stating "no harm to any patients (that we know of)," Quest shows a lack of respect for the turmoil it has caused to patients and physicians. Of course, lawyers have a hand in these public statements. Still, I come from the old-fashioned school of values, where admitting a mistake is the right thing to do and the first step to rebuilding trust with my customers and my friends. TDR

Inaccurate Results + Quest Dominates News Cycle

From the New York Times to CCN News, Quest's Inaccurate Vitamin D testing is a big story

CEO SUMMARY: Most laboratory professionals don't know it yet, but significant changes occurred to the entire lab industry last week. After Quest Diagnostics Incorporated acknowledged that it was retesting tens of thousands of patients because 7% of the Vitamin D results it reported during an 18-month period were inaccurate, a blitz of newspaper headlines and television news coverage of the story alerted Americans to the problem.

LAST WEEK, **Quest Diagnostics Incorporated** found itself in the midst of a media firestorm, as the nation and the world heard Quest admit that it had reported inaccurate results for Vitamin 25(OH) D tests to tens of thousands of patients.

It was THE DARK REPORT which scooped the national media and first broke this important story in its issue dated December 22, 2008. Until then, even the laboratory industry was unaware that Quest Diagnostics was conducting a voluntary retest program, notifying what THE DARK REPORT believes is actually hundreds of thousands of patients who were given inaccurate Vitamin D results by Quest during 2007 and 2008.

From the *New York Times* and *USA Today* to CNN and ABC's Good Morning America show, news coverage last week centered around such themes as "nation's largest lab acknowledges erroneous Vitamin D tests" and "can you trust your lab test result?" Across the country, local newspapers ran stories about the problems with Vitamin D testing at Quest Diagnostics.

The negative publicity put Quest Diagnostics in a damage control mode. In speaking to reporters, it constantly stressed the theme that this was just a small matter and it was not likely that patients had been harmed because of an inaccurate Vitamin D test result.

The **Associated Press**, in its story published on January 9, interviewed Gary Samuels, Quest Diagnostics' Vice President of Communications, who said "Last year, we did have an issue in a few of our labs that affected a small minority of tests in those labs. We identified the problem ourselves. We corrected the problem. We noti-

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fied doctors and other customers and offered free retesting."

However, Samuel's characterization of the issue as a "small minority of tests in those labs" needs to be viewed in two dimensions. First, as a percentage of Vitamin D tests performed during that time. Second, in terms of the actual number of patients to whom Quest Diagnostics reported inaccurate results.

When studied in these two dimensions, Samuel's "small minority of tests" actually represents a major quality control/quality assurance failure by an accredited, licensed laboratory organization. It also becomes a failure which directly affected hundreds of thousands of patients and tens of thousands of physicians. The two dimensions are analyzed below.

➤7% Of Results Were Wrong!

How many inaccurate Vitamin D tests did Quest perform? In the January 9th Associated Press story, Wael A. Salameh, M.D., Medical Director, Endocrinology at Quest Nichols Institute in San Juan Capistrano, disclosed the number of inaccurate results. The AP reporter wrote "Eventually, the company [Quest] flagged about 7% of vitamin D testing results from 2007-2008 as questionable, although it believes the problem was much smaller. Generally, the readings obtained on the questionable tests were higher than they should have been, Salameh said. In some cases, though, it was hard to discern a pattern."

This is a remarkable concession. Quest Diagnostics is revealing that, for a period lasting as long as 18 months, 7% of the test results it reported from its high-volume home brew LC-MS/MS assay for Vitamin 25(OH) D were inaccurate!

Pathologist and laboratory scientists must ask themselves this question: Does the American public expect their laboratory provider to report an accurate lab test result 93 out of 100 times?

Most people know the correct answer to that question. The media immediately recognized how Quest Diagnostics had betrayed the trust of the American public. Journalists knew this was a big story and would catch the attention of the American consumer. That is why, on Thursday and Friday last week, so many news outlets issued screaming headlines about "inaccurate lab test results."

➤May Have Misled Patients

For the same reason, it is why ABC's Good Morning America did a 3-minute feature on Friday, January 9, titled "How Accurate Are Blood Tests?" Its opening statement was that "Quest Diagnostics alerted doctors that many Vitamin D tests performed over the past two years were wrong and could have misled patients into thinking they are healthier than they actually are."

Trust is the theme here. Consumers don't expect an accredited, licensed medical laboratory of good standing to deliver accurate test results only 93 out of 100 times. Even Samuel's "small minority of tests" is a big deal with the American public.

Having looked at the percentage of inaccurate tests results as one dimension to this important story, the actual number of patients to whom Quest Diagnostics reported inaccurate Vitamin D results represents a second dimension.

➤Retesting 490,000 Patients?

THE DARK REPORT estimates that the number of inaccurate Vitamin D test results probably ranges between 350,000 and 490,000. Information on the Web indicates that Quest Diagnostics was performing 500,000 Vitamin D tests per month last summer. Factor in a rate of growth in specimen volume over the previous 18 months and one estimate is that Quest Diagnostics performed a total of between 5 million and 7 million Vitamin D tests during the time in 2007 and 2008 when it admits it was reporting inaccurate results at the 7% rate.

Quest's Inaccurate Vitamin D Tests Dominate the News Cycle–But Where Are Pathologists?

IT WAS NATIONAL NEWS LAST WEEK that the nation's biggest laboratory company had admitted to a clinical testing fiasco of immense consequences. But absent from major news reports was any other lab industry voice other than Quest Diagnostics Incorporated.

For the entire laboratory profession, this fact may turn out to be just as important to the future of laboratory medicine as the consequences from the public disclosure by Quest Diagnostics of systemic failures with its Vitamin D testing program, and how it reported inaccurate results to patients for a period lasting as long as one and one half years. At a minimum, that's because the internal lab testing problems at one high-profile lab company could cause lab regulators to tighten licensing and regulatory requirements in unwelcome ways.

News reporters seemed to have no problem locating experts to discuss how inaccurate Vitamin D test results may have been harmful to patients or to inform consumers about the role Vitamin D plays in maintaining health. But THE DARK REPORT is unaware of a news story or television news segment which included comments by a non-Quest pathologist on different aspects of this headline news story.

Speaking For Lab Medicine

Are pathologists and medical laboratory scientists invisible to the nation's news media? Is there no professional lab organization that reporters consider to be a credible source of experts on laboratory medicine? Or, was this a story that was "too hot" and too full of professional dynamite for any individual pathologist to volunteer an interview with a major news outlet?

Pathologists complain regularly that the public does not recognize the essential services they provide. Here was an opportunity for the pathology profession to provide objective information to Americans, along with relevant information about why this systemic failure with Quest Diagnostics' Vitamin D testing program is an exceptional event in modern medicine.

THE DARK REPORT asks these questions because laboratory medicine stands at the threshold to the era of genetic medicine. Already the first elements of personalized medicine—informed and supported by molecular diagnostics—are gaining clinical acceptance. News stories about breakthroughs in cancer diagnosis and treatment appear regularly, for example.

Preparing For Genetic Age

However, genetic testing and molecular diagnostics require a much more complex mix of technology, clinical expertise, and laboratory science to properly perform than, say, a test such as Vitamin 25(OH) D. It is time for the pathology profession to establish its "brand" and name recognition with the media, as well as among consumers, health policymakers, and elected officials. As society makes decisions about how to respond to genetic medicine, pathologists and lab scientists need a voice in that debate.

But to have credibility and authority going forward, laboratory professionals must have a united, public front. The alphabet soup of acronyms from lab specialty associations and societies becomes a barrier for news reporters seeking lab professions to provide expert opinion on specific topics in laboratory medicine, as well as to speak authoritatively for the laboratory medicine establishment.

It appears that the news of Quest's problems with Vitamin D testing has caught the lab industry flat-footed and unprepared. That is why the voice of the laboratory profession was missing from the rancorous headlines of last week. It is time to act, so that in the next news cycle dealing with a laboratory issue, lab professionals have the opportunity to be part of the discussion in a positive way.

If it is true that Quest Diagnostics is sending notification and retest letters to as many as 490,000 patients across the United States, then that fact is a headline story by itself! Quest Diagnostics was lucky to keep reporters from uncovering the accurate and total number of patients who are involved in this retesting program.

Last week's news headlines changed the lab industry status quo in two important ways. One, it made a large number of Americans aware that not every laboratory test result can be trusted—nor is the quality of a test result from one laboratory necessarily comparable to the quality of a lab test result from another laboratory. In fact, the ABC Good Morning America segment interviewed a private practice doctor (not a pathologist) who made exactly that point.

Lab executives with a long memory will remember that the last time the lab industry made the news cycle in this way, it was following revelations, in the 1980s, of sink testing by a cytology laboratory in California. That media coverage spurred Congress to pass the Clinical Laboratory Improvement Act (CLIA) to reform lab testing practices and prevent these types of abuses. It is not unreasonable to believe that this current round of news headlines could be used as justification for lawmakers to further regulate laboratory testing activities.

➤Search Engine Links

Two, at a minimum, Quest Diagnostics is now identified with "inaccurate testing" in the public mind. Put "Quest" and "Vitamin D" together in a search on Google, Yahoo, MSN, and other sites. At the moment, almost all of the entries returned will have Quest—along with such words as inaccurate, erroneous, errors, false, and wrong—in the description line. This Internet record will follow Quest Diagnostics for years into the future. Some companies have changed their names simply to disassociate themselves from this type of bad publicity. Think of **National Medical Enterprises** (NME), which changed its name to **Tenet Healthcare Corporation** in 1994 to leave behind all its legal and public relations problems.

In addition to the two changes noted above, both Quest Diagnostics and the lab industry at large may face several broad, relevant questions.

First, will the decision by Quest Diagnostics to drop the use of a popular, FDA-cleared lab test and instead substitute a home brew method—to test specimens from millions of patients in a high-volume setting—now be viewed critically by regulators, legislators, and the press? Armed with hindsight and looking back in time, can it be argued that ethical and legal considerations were outweighed by a laboratory's goal, among other objectives, of using a home brew to reduce operational costs?

➤Home Brew vs. FDA-Cleared

Another element may attract regulatory scrutiny. Quest Diagnostics has heavily promoted its tandem mass spectrometry Vitamin D assay to doctors as offering: 1) "gold standard" analytical accuracy; and 2) capable of reporting D2 and D3, along with total Vitamin 25(OH) D. This marketing/sales plan is designed to encourage physicians to cease using the FDA-approved immunoassay in favor of the Quest home brew assay. Again, with hindsight, might regulators view this as one more reason why sanctions should be levied against Quest? Could Congress use this as one more reason to give the FDA increased oversight over laboratory-developed tests (LDTs)?

The key insight here is that much of the short-term news value in this story has to do with the public's reaction to news that a major laboratory acknowledged issuing inaccurate lab test results to large numbers of patients for a period of almost two years. It is the long-term consequences of this story that will may well end up altering—in unwelcome ways—several industry practices that are common today. TDR

Labs Need to Respond To Inaccurate Results

In 2004, ongoing failures in HCV, HIV testing at a Baltimore hospital lab became national news

CEO SUMMARY: What does a lab do when it discovers that it has reported inaccurate test results? In 2004, a turnaround team arrived at the laboratory of Maryland General Hospital in Baltimore to deal with the consequences of a failed infectious disease testing program. For about two years, the lab had reported inaccurate HCV and HIV results. One member of that turnaround team shares lessons learned that pathologists can use to develop effective contingency plans for their own labs.

NEWS THAT THE NATION'S LARGEST LABORATORY reported erroneous Vitamin D results to as many as hundreds of thousands of patients during 2007 and 2008 became national news last week.

For pathologists and lab managers, it is a reminder that every laboratory should have a contingency plan that addresses the consequences of having reported inaccurate results, particularly when large numbers of patients are involved.

Richard Ouellette is one laboratory professional who has direct experience in dealing with a laboratory's internal failures and the unfavorable national news coverage that results. In 2004, he was among the first lab experts retained to correct the deep-rooted, systemic problems in the laboratory at Baltimore's 242-bed **Maryland General Hospital** (MGH).

Maryland state health officials had determined that over the 14 months beginning in June 2002, HIV and HCV testing done at the hospital's laboratory had produced unreliable results and the *Baltimore Sun* immediately made this into a national story. Public health officials estimated that, as a result of flawed testing during that time, at least 4,500 individuals tested for HIV and HCV had been given potentially inaccurate results. *(See TDRs, April 26 and May 17, 2004.)*

In the wake of this lab testing scandal, MGH President and CEO Timothy D. Miller resigned. The hospital's Director of Pathology and Laboratory, Philip J. Whalen, M.D., also resigned. James Stewart, Administrative Director of Laboratory Services during the time of the lab's systemic failures, was placed on leave and resigned several months later.

Role As Interim Lab Manager

Ouellette, who currently is President and CEO of **Management Decision Systems, Inc.**, in Holden, Massachusetts, came to Maryland General Hospital as a contractor with **Chi Solutions, Inc.** He shared the interim laboratory manager's role at the MGH lab and then shortly thereafter took over as project manager. His company's quality management systems, MAST (Management Accountability, Service & Staffing Tracker), and the ORF Tracker risk management system, were installed at the MGH laboratory during this time as well.

In this role, Ouellette had input in shaping the laboratory's response to the public and the media, while taking the corrective actions needed to find the patients (and their physicians) who had received the erroneous results. These doctors and patients were then notified of the inaccurate results, along with the need to perform a retest.

Massive Effort For Retest

This required a massive effort. The retest strategy and plan at Maryland General Hospitals was developed by a 15-member multidisciplinary team. Included were pathologists, physicians, laboratory consultants, executives and members of the community.

THE DARK REPORT asked Ouellette to share his experience and make recommendations about how a lab should react when errors are made, such as in the case of the erroneous Vitamin 25(OH) D lab test results that **Quest Diagnostics Incorporated** has admitted reporting to physicians and their patients during 2007 and 2008.

"When the public learns that a laboratory allowed systemic errors and reported inaccurate results to patients, that laboratory will find itself in the center of a hurricane of criticism," observed Ouellette.

Unfavorable Publicity

"This is the moment when a good crisis management plan and a coordinated team effort makes all the difference in whether a laboratory can recover from the unfavorable publicity—and whether the laboratory will be able to re-establish trust with its referring physicians and patients," he added. "Every lab should have a contingency plan which addresses two dimensions of the problem. The most important dimension is mandated by CLIA and relevant regulatory processes, informed by ethics and the appropriate clinical issues which come into play. The second dimension is the public reputation of the laboratory.

"After any mistake, there are processes mandated by CLIA to which labs must adhere," continued Ouellette. "The goal of these quality systems is to establish standard operating protocols and quality control programs so that, as the laboratory conducts testing, the results are deemed accurate and reflective of each patient's condition.

"The quality process takes into account the pre-analytical and the analytic testing processes," he noted. "One goal of these protocols is to immediately identify and correct errors. That means corrections should be made before any results are reported to physicians and their patients.

Inaccurate Test Result

"Errors happen in every laboratory," Ouellette continued. "An inaccurate result could go out for any number of reasons. If either the laboratory or the physician discovers the inaccurate result, the protocol is for the lab to immediately retest, assuming they still have the same specimen. If the result of the retest is different from what was originally reported, then a corrected report process takes place.

"The initial result remains on the patient's record," he said. "It is highlighted manually or electronically to: 1) let people know that it was the wrong result; and, 2) guide them to the corrected report. The lab notifies the physician of that error. The laboratory also generates an incident report and takes corrective action. Next, an assessment takes place to determine what caused the incorrect patient test result.

"Equally important in this process is to implement corrections to procedures and processes that, when followed, verify that the error will not take place in the future," advised Ouellette. "Ultimately, the laboratory must conduct a rigorous root-cause analysis to determine what caused the error and how to prevent it from happening in the future. Some laboratories will have already performed a FMEA (Failure

Mode and Effects Analysis), a proactive tool and quality method that enables the identification and prevention of testing process errors before they occur. The goal of this effort is to avoid adverse events that could potentially cause harm to patients, employees or others in the pre-analytic, analytic, and post-analytic phases of the testing process.

Root Cause Analysis

"The root cause analysis will help find the breakdown in the lab's existing testing processes, as well as breakdowns in the lab's quality assurance and quality improvement processes," he said. "By the way, all lab accreditation agencies expect that, in these situations, the laboratory will do a root cause analysis and implement the required corrections to ensure that this source of inaccurate test results does not recur.

"What was different about the systemic problems at Maryland General Hospital—and what we are learning about failures in Quest Diagnostics' Vitamin D testing program—is that errors at these labs reached what I will call an almost 'catastrophic' level," Ouellette related. "It wasn't a random event that happened, after which the lab then isolated the cause and fixed the problem.

Thousands Of Patients

"At the MGH lab, thousands of patients over several years were involved," continued Ouellette. "Quest Diagnostics is telling the press that its systemic problems with Vitamin D testing occurred during an 18-month period. It has acknowledged that about 7% of Vitamin D results were inaccurate during that period. So it is likely that a very large number of patients are involved in its retesting program.

"In each example above, the laboratory must answer the question: "Do we know if the error caused harm to a patient?" commented Ouellette. "Generally, determining if there was any harm to a patient comes down to a judgment call on the part of the medical director who is ultimately responsible for laboratory operations. It also involves an intensive investigation of the affected patient's medical record, their diagnosis, and any other testing that may have been performed at the time.

Whistleblowers Raise Flag at Maryland General's Lab

NEWS ABOUT CATASTROPHIC LAB TEST ERRORS in the laboratory at Maryland General Hospital broke on March 10, 2004. State health officials found, beginning June 2002, that HIV and HCV testing done at the hospital's laboratory had produced unreliable results over 14 months. The *Baltimore Sun* was first to report this story.

Within days of this disclosure, public health officials estimated that at least 4,500 individuals tested for HIV and HCV had been given potentially inaccurate results during the 14-month period of flawed testing.

"I'm really quite disturbed. They [laboratory personnel] apparently knew there was a problem," stated Baltimore Health Commissioner Peter C. Beilenson at the time of the news. Beilenson and Secretary of the Maryland Department of Health Nelson J. Sabatini both stated that two inspections of the laboratory by state officials in January 2004 had uncovered other potential problems in how the laboratory was operated.

Two days later, on March 12, 2004, came another startling disclosure. A medical technologist formerly employed by the hospital laboratory had sent a letter to state health officials in December describing serious safety and accuracy problems in the MGH laboratory. Now it was learned that this med tech was infected with both HIV and HCV, which she attributed to exposure while operating the HIV/HCV testing instrument in the lab.

Public news that hundreds of patients may have received inaccurate results from their HIV and HCV testing created a public relations disaster for the hospital.

"I can share with you the process we used to address these systemic problems at the MGH laboratory," offered Ouellette. "It was a time when the lab and the entire hospital were undergoing intense scrutiny by Maryland health authorities, CMS officials, as well as by inspectors from **The Joint Commission** (then JCAHO), and CAP. We were meticulous in our assessment of the issues. MGH followed the ethical high ground in dealing with affected patients and physicians, as well as with the media and health officials.

"If the laboratory has good reasons to believe that no patient was harmed, then the laboratory can start to make corrections that will prevent this type of error from happening again," he stated. "However, if there was patient harm—or if the lab is not sure if any patient was harmed—then the laboratory must institute the patient retesting protocol.

A Judgment Call

"In resolving the known lab errors at Maryland General Hospital, the judgment of the new medical director was to follow the patient retesting protocol," Ouellette explained.

"However, this is not a simple black/white decision, particularly when inaccurate results were reported by the laboratory to large numbers of patients over a period of several years," he added. "The medical director makes the decision to institute a patient retest protocol, which then triggers several questions that the lab must answer.

"Some labs might ask, for example, 'Is there any wiggle room when making this assessment?' Yes! Absolutely there is wiggle room," stated Ouellette. "At the same time, the laboratory must keep in mind that what keeps labs on the straight and narrow is intense regulatory scrutiny and their continued ability to provide patient care in their community.

"Inspectors from the state health agency, the federal **Centers for Medicare & Medicaid Services** (CMS), or the **College of American Pathology** could show up at any time to inspect the laboratory," he explained. "Those inspectors could say, 'Wait. You didn't do the error assessment appropriately,' or 'We disagree with your assessment.'

Billing For Medicare Testing

"If CMS determines there's a problem, it can affect a laboratory's ability to bill for testing provided to Medicare/Medicaid beneficiaries and be paid for services," Ouellette added. "The pathologist's license can be jeopardized or revoked as well.

"If a mistake occurs in a hospital laboratory, it can cause the parent hospital to come under regulatory and public scrutiny that would affect the hospital's ability to attract patients," he stated. "For all these reasons, most laboratory professionals will play it by the book when a mistake is made that might affect patient care, taking careful steps to properly correct that lab test error.

"In our case, because the lab test errors had occurred during a two-year period, we knew we would have to collect new specimens from many patients before conducting the retest—but first we would have to locate these patients to notify them of the inaccurate lab test result and arrange to collect a new specimen," recalled Ouellette.

"Another question that we had to answer for each individual patient was how the retest might have different clinical significance for the individual patient," continued Ouellette, "After all, the health status of patients changes from day to day. Patients may be undergoing therapy. The laboratory must collect all this information to make an informed decision. It is responsible for reporting inaccurate results to the physician and the patient. What impact could those inaccurate results have had on that patient's course of treatment?

"Inaccurate Vitamin D results reported by Quest Diagnostics illustrate

Hostile Press and Poor Morale Just Two Challenges at Maryland General Hospital Lab

WHEN RICHARD OUELLETTE, FACHE, MT(ASCP)H, stepped in as an interim project manager at Maryland General Hospital (MGH) in 2004, he faced one of the most difficult challenges a lab manager can face. He was charged with coordinating a team to identify and correct potentially thousands of lab tests errors while rebuilding the laboratory's processes and protocols from the ground up.

"At MGH, most errors were produced from a faulty instrument," Ouellette recalled. "A procedure was modified incorrectly without being documented properly and that procedure went on for about two years. Over that time, about 4,000 to 5,000 patient tests went out with incorrect results. There were other procedural issues with this lab that needed to be corrected. It was a big challenge to correct flawed procedures so these inaccurate results would not happen again.

As Many As 5,000 Patients

"We reviewed all the patient records at the MGH laboratory and determined that 8,000 samples—representing between 4,000 and 5,000 patients—were likely to be involved in the problems with HIV and hepatitis testing," he explained. "During our detailed examination of each patient's medical records, we wanted to determine if any patient was harmed because of inaccurate lab test results. According to CLIA, that's the key issue in any case involving a lab error: was any patient harmed? An important secondary question is: how were patients affected?

"When the public learned that thousands of patients may have received inaccurate results, this created a hostile press environment that contributed to a morale problem in the MGH laboratory," recalled Ouellette. "The *Baltimore Sun* was very critical of the hospital, but the hospital had made a decision not to fight the issues in public or in the press.

"Instead, the hospital issued progress updates and explained what it was doing," Ouellette said. "Otherwise, it didn't comment. That's quite different from other situations in which I have worked, where hospitals hired public relations consultants to respond to criticisms from the press and the public.

"Another challenge in restoring this laboratory into a reliable, quality testing organization was the need to work with different accrediting and licensing agencies," he said. "During my time at MGH, the laboratory was undergoing inspections by federal and state agencies, as well as the College of American Pathologists and the Joint Commission. The multiplicity of inspecting agencies made the implementation of our laboratory improvement plan much more difficult. Our team needed to balance our limited resources to both respond to these inspections while continuing to improve the laboratory's performance.

"During our patient retest program, MGH used outside help to locate patients who had been tested within the previous two years," said Ouellette. "Obviously patients move in and out of the city. Some patients are transients. Other patients are elderly and some may haved died since the testing was performed. These are some of the obstacles involved when notifying patients of inaccurate results and arranging to perform a retest.

"The program to notify physicians and patients, then perform the retesting, required about two years," he concluded. "On the first round of contacts, we reached about 70% of the patients. Toward the end of the process, it became progressively harder to move the total number of patients contacted and retested from 95% to 98%."

this challenge," said Ouellette. "Assume that a physician closely monitoring his/her patient had three vitamin D tests done over 18 months. The lab determines that the first Vitamin D test was inaccurate and the second two test results were accu-

rate. What is the proper, ethical course of action for the laboratory in this example?

"Does that lab let the first inaccurate Vitamin D result go, because it has provided accurate results on the two most recent tests?," he asked. "My perspective is that these questions are clinical, meaning the medical director should answer them.

"Even though the medical director must make the first assessment, my recommendation is that, when the issue is questionable, the laboratory has the responsibility and ethical obligation to notify the attending physician, advise him of the lab test error and its possible consequences to the patient's health. That gives the attending physician the relevant information he/she needs to provide proper care to the patient.

➤Due Diligence

"The next question is: What happens if the physician or the patient doesn't cooperate in your lab's effort to do a retest?" he asked. "In that case, you conduct due diligence and document your efforts to reach the physician and the patient. The laboratory did what was reasonably expected by a community's standard of care. Now it becomes a legal question and your lab has documentation of its actions."

Ouellette next turned to another issue that is triggered when a laboratory has reported inaccurate test results. "As the patient retest protocol proceeds, the laboratory must next address its obligations to the payers," he stated. "The laboratory cannot bill for a retest that is being performed because the original test was erroneous.

"The lab must eat the costs of retesting," said Ouellette. "Moreover, the laboratory must assume all of the costs associated with the retest program. At MGH, the cost of the testing process was actually the least costly part of the effort. The logistical nightmare of locating and informing physicians and patients was the most challenging and incurred the greatest cost.

"It's important to remember that mistakes happen," noted Ouellette. "When mistakes occur, it's best to have an effective chain of command in the laboratory and open communication throughout the organization. More importantly, the laboratory needs to foster a working environment where staff understands that the potential for errors exists—and when errors are discovered, staff can do the right thing to: 1) report the error; 2) correct the cause of the error; and, 3) notify the referring physician and the patient about the error and arrange for retesting."

"Staff in your laboratory want to do a good job," noted Ouellette. "They want to provide accurate, high quality test results to every patient. At MGH, we worked hard to foster communication and a nurturing work environment. A constructive atmosphere may be the single most important key to identifying errors and making effective corrective actions."

In laboratory medicine today, there are not many lab professionals who have had to clean up after a major laboratory testing failure. Ouellette's experience at MGH is unique. The unfolding story about systemic failures in Vitamin D testing at Quest Diagnostics is a reminder to all pathologists and lab managers that the best crisis or contingency plan is to always produce reliable, accurate lab test results.

➤Be Prepared

But when things go wrong in a laboratory, it is important to be prepared. That means having a plan to contact those physicians and patients who may have recieved inaccurate results, as well as a plan for handling what are likely to be hostile news reporters. The high-profile news coverage of the problems at Maryland General Hospital's lab in 2004 and now at Quest Diagnostics during 2007-2008 demonstrate how quickly a laboratory's fortunes can change. **TDR**

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Obituary

Dennis Monahan of ARUP Dies on Christmas Eve

He was ARUP's first sales representative and contributed to the lab's growth for 24 years

HE HAD A CAREER THAT SPANNED the birth of the esoteric/reference testing industry and its evolution into a major source of advanced diagnostic services to the nation's hospitals and commercial laboratory companies.

Dennis Patrick Monahan was Vice President for National Contracts at **ARUP Laboratories** in Salt Lake City, Utah. Colleagues and friends were stunned at the news that Monahan died on Christmas Eve, December 24, 2008, as a result of a sudden and unexpected massive heart attack.

Dennis P. Monahan
1948-2008

Monahan was widely-known throughout the laboratory profession. He was regularly in attendance at national lab meetings across the country and was actively involved in a variety of lab industry initiatives.

ARUP's First Sales Person

Monahan held the unique distinction of being the first sales person hired by ARUP in its earliest days. ARUP was founded in 1984 and Monahan joined the company in 1985. In his 24 years of service at ARUP, Monahan played a continually expanding role in helping the company grow into one the nation's first-rank providers of esoteric and reference testing.

A California native, Monahan was born in Pasadena on October 8, 1948. Because his father was an Air Force pilot, Monahan grew up as the proverbial military brat, living in such places as California, Alaska, Florida, New Mexico, and upstate New York. Following service in the U.S. Army, he attended Western State College in Gunnison, Colorado.

Upon graduation, Monahan worked for several medical lab companies doing sales and account management before accepting a professional sales position at the newly-formed ARUP Laboratories. His contributions led to positions of increasing responsibility, as he served in the roles of account representative, national sales manager, and most recently as Vice President for National Contracts.

It was Monahan's genteel nature and winning personality that distinguished him and earned the respect of those who knew him. ARUP Laboratories' CEO and Chairman of the Board, Carl R. Kjeldsberg, M.D., aptly characterized Monahan by saying "His humble, honest, gentleman's approach was the opposite image most have of salespeople."

It was not just ARUP Laboratories that benefited from Monahan's skills and leadership. He was actively involved in advancing the profession of laboratory medicine through his participation in many industry groups and activities. For that reason, his unexpected death represents a loss for the entire profession. TDR

Lab Conserves Blood When Drawing Patients

➤Rhode Island hospital laboratory has lead role in encouraging adoption of transfusion-free medicine

➤➤CEO SUMMARY: New attention on both the risks associated with blood transfusions and the cost of blood products is triggering action by the nation's hospitals. At the 719-bed Rhode Island Hospital, the laboratory is on the front line of the hospital's blood management initiative. One change in long-standing practices is to encourage phlebotomists to draw only the minimum amount of blood required for lab testing. However, smaller specimens require changes to lab operations.

DRAWING BLOOD FROM PATIENTS FOR LAB TESTING has long been a routine task in every hospital nationwide. Every day in every healthcare facility, phlebotomists working for laboratory departments fan out to take samples from patients.

But this routine phlebotomy task is about to undergo a major change as more hospitals recognize that what's best for their laboratory is not necessarily what's best for patients. "In fact, it may be best to conserve the amount of blood taken from each patient for each procedure," said Kevin T. Wright, Program Manager for Transfusion-Free Medicine & Surgery at the 719-bed **Rhode Island Hospital** (RIH) in Providence. "Some patients may prefer to conserve their blood, while for others this is a necessity due to anemia."

This trend is linked to the dramatic increases in the cost of blood products. In response, hospitals such as RIH launched programs to educate all clinical staff about the value of blood conservation. For three years, Wright has devoted full-time effort at RIH to working on these issues with the clinical staff. He finds the laboratory is the ideal department to spearhead the hospital's blood conservation efforts.

"Hospitals are adopting blood conservation protocols, in part because of the high costs of purchasing blood and blood products," noted Wright. "There are also patient safety issues associated with transfusing blood—a process that is not without risk and can introduce infectious agents to patients. As well, some patients simply prefer not to receive blood from someone else while other patients cannot afford to lose much blood during procedures because they may already be compromised by pre-existing conditions."

➤One Goal: Draw Less Blood

One primary goal of the blood conservation program is to draw as little blood from patients as possible. This objective recognizes two realities. One, some patients can become anemic, in part because of blood drawn for laboratory tests. Two, this program accommodates the growing number of patients who prefer to conserve their blood.

"We must be mindful of the need to prevent a patient from becoming anemic,"

stated Marilyn McAllister, Director of Pathology Administration at RIH, who works closely with Wright. She is the lab's point person in the effort to change the hospital staff's awareness of the need for blood conservation. "We also need to recognize that some patients now want to conserve their blood. They question every request to draw specimens.

Clash With Today's Reality

"That concept clashes with the reality of long-established phlebotomy practices," continued McAllister. "For example, often the lab staff will ask, 'What's the big deal if we draw three tubes versus four tubes?' In our hospital's blood conservation program, the answer to that question is, 'if we can meet the need for a set of lab test orders with one tube, that's what we should do.'

"It is common practice for phlebotomists to draw ample quantities of blood because it makes the lab's job easier," observed McAllister. "Instead of taking one tube from a patient, a phlebotomist will draw four tubes simply so the lab will not need to aliquot.

"Drawing so much blood is convenient for a lab because chemistry gets its own tube, clinical gets its own tube, and toxicology gets its own tube," she said. "This common practice is changing here at Rhode Island Hospital. Now we stress the importance of minimizing the quantity of blood we draw from each patient.

Drawing Less Blood

"Drawing less blood means more handling of tubes in the lab and perhaps using smaller tubes," she explained. "Our lab and our phlebotomy staff must adjust to these new concepts in order to accommodate this new focus on blood conservation."

The laboratory at RIH, which performs six million tests per year, recently converted to a new laboratory information system (LIS). "As we built the database in this new LIS, we had the

Blood Draw Practices Are Changing in Hospitals

IN AN EFFORT to limit the number of patients who get transfusions, hospitals are developing initiatives to recycle blood and prevent anemia. These efforts also help hospitals to cut the cost of purchasing blood and blood products while also improving patient care by helping to eliminate risks.

Traditionally, physicians believed blood was safe, and so saw no reason to withhold it from patients. "But the modern view is that, when we give blood unnecessarily, we cause measurable harm to patients," said Timothy Hannon, Medical Director of the Blood-Management Program at **St. Vincent Indianapolis Hospital**, which is part of **Ascension Health**. "We must be sure we give the right dose of blood to the right patient at the right time, and make much smarter use of blood products." Hannon was quoted in an article in *The Wall Street Journal*, "Hospitals Seek to Limit Use of Transfusions."

Hospitals are developing guidelines for when transfusions are necessary, and checking patients for anemia before surgery.

The cost of a unit of blood has more than doubled over the past decade, and hospitals spend an estimated $25 billion to buy, to process, and to transfuse about 30 million units a year, according to the *WSJ*. Also, research shows that donated blood can cause infections, complications, and death. A recent study showed that blood stored for 29 days or more is associated with a higher rate of infections among patients getting transfusions.

At the same time, a technical advisory panel for the **Joint Commission** has developed 19 blood management performance measures for hospitals and will be making recommendations on the issue. The Joint Commission has decided that the panel should address blood conservation, appropriate transfusion, and a patient-centered focus regarding blood use in U.S. hospitals. The panel's recommendations are expected soon.

opportunity to discuss how many tubes we should draw from each patient. Are we going to draw all the tubes we normally draw because it's convenient for us? Or will we draw just the number that's best for the patient? We are designing our new database to help lab staff and phlebotomists make the best decision about how to reduce the quantity of blood required from a patient."

As a pioneer in the concept of implementing blood protocols, the RIH lab encounters some interesting obstacles. "Probably the single biggest problem we face in our goal of reducing the amount of blood we draw is the limitations imposed on us by vendors," declared McAllister. "All the vendors make instruments, robotic lines, and automated systems that work only with tubes of a certain size.

"As a consequence, our lab doesn't have the flexibility it needs to accommodate different—and often smaller—tube sizes," she noted. "For example, in circumstances where we could use pediatric tubes, the demands of the automated line and the analyzers force us to continue using larger tubes. We face the trade-off of losing the efficiency from automation were we to use the pediatric tubes.

Equipment Challenges

"It's not a surprise, then, that our interest in supporting blood conservation now shapes our equipment purchases," she continued. "Coagulation is next in our instrumentation upgrade program.

"We want to connect this new coag system to an automated line and that raises a number of questions. What tubes can we use in this new system?" asked McAllister. "Are we limited to a certain tube size? Can we find an instrument platform that allows us to use multiple-size tubes—thus allowing us to draw pediatric tubes whenever that lesser quantity meets our needs?

"These are valid questions, but we recognize that vendors are probably not ready to support us in our blood conservation efforts," she explained. "It means we will be educating our vendors about the need to accommodate blood conservation. This is one way in which our hospital's blood management program has created new questions and new requirements to which vendors will need to respond.

An Eye Opener

"This effort has been an eye-opener for all of us, especially given that the concept of blood conservation is not new," she said. "Most labs are accredited by the **College of American Pathologists**, which has a general question on its accreditation checklist that asks if the laboratory has taken steps to minimize the amount of blood drawing. Of course, every lab manager checks it off as 'yes.' However, I don't think many lab professionals take these efforts seriously. And few labs ever get blood conservation as a deficiency. That is changing at our institution, as lab staff and lab administration actively work on this issue."

Wright agreed, saying that New England lags behind some other areas of the country in adopting these programs. "Before I came to Rhode Island, I worked with hospitals in California and Illinois which had already implemented successful blood conservation programs," he stated. "I also consulted with hospital that were developing their own programs. By contrast, hospitals in the upper parts of the Northeast have been slow to adopt blood management and blood conservation measures. That is one reason our hospital is considered to have the premier blood-management program in New England."

THE DARK REPORT observes that blood conservation represents a fundamental mindset change in how a lab interacts with its patients. It puts the laboratory on the path to patient-centric services. **TDR**

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ASCP Awarded PEPFAR II Funds for Lab Assistance

ASCP members now serving 15 PEPFAR countries to help improve lab testing services

CEO SUMMARY: With new Congressional authorization and funding of $48 billion, PEPFAR II—a second five-year initiative to help targeted countries battle HIV, AIDs, tuberculosis, and malaria—is about to get under way. To better support diagnosis and management of HIV/AIDs patients, some PEPFAR funds are designated to expand laboratory testing services in countries with high prevalence rates of HIV/AIDS. ASCP's funding award will support laboratory training events and technical assistance to labs in 12 PEPFAR countries.

LABORATORY TESTING SERVICES continue to play an essential role in supporting patient treatments under PEPFAR (President's Emergency Plan for AIDS Relief). One of the first laboratory organizations to receive funding in the current budget cycle is the **American Society of Clinical Pathology** (ASCP).

ASCP was awarded $3.9 million in PEPFAR funding this fall by the U.S. **Centers for Disease Control and Prevention** (CDC). The funding is for the first year of the nation's second five-year PEPFAR initiative. Last year, ASCP received $2.8 million in PEPFAR funding to develop and implement laboratory training programs in 12 of 15 PEPFAR countries, mostly in Africa.

Many Lab Groups Involved

Other lab associations that received funding under PEPFAR include the **Association of Public Health Laboratories** (APHL), the **American Society for Microbiology** (ASM), and the **Clinical Laboratory and Standards Institute** (CLSI).

In the first five-year PEPFAR cycle, the United States spent $15 billion. For this second five-year cycle, called PEPFAR II, Congress allocated $48 billion to treat patients who have AIDS, malaria, and tuberculosis. Of the total allocated, $39 billion is going for AIDS-related treatment and prevention efforts.

Since 2004, ASCP and its volunteers have trained more than 1,400 laboratorians in such areas as laboratory management, phlebotomy, hematology, chemistry, and CD4 testing. These newly trained laboratory professionals then serve in laboratories which provide monitoring services to HIV/AIDS patients in PEPFAR countries.

The CDC's new funding award for PEPFAR II allows ASCP members and staff to continue these training programs. The emphasis is on providing laboratorians in PEPFAR countries with best practices that will result in quality testing. One cornerstone of this effort is to emphasize the importance of quality control and quality assurance. Both are fundamental elements critical in moving a laboratory toward accreditation.

"ASCP's scope of work under PEPFAR has grown in the last few years," said Barbara Hoffman, ASCP's Director of Global

Outreach. The objective is to build laboratory services capable of high quality laboratory testing to support the diagnosis and monitoring of patients with HIV/AIDS in resource-limited countries."

U.S. Labs And PEPFAR

Laboratory testing support for PEPFAR activities is a little-known story in the United States. The CDC supervises a program to develop and support lab testing services within PEPFAR countries. Volunteers from laboratory groups, including ASCP, travel to countries in Africa, South America, and the Caribbean to train laboratory staff and help laboratory organizations achieve accreditation under international standards. The goal is to build a laboratory infrastructure that will provide reliable, accurate laboratory testing that supports the diagnosis and monitoring of patients with HIV/AIDS in resource-limited countries.

PEPFAR II (*www.PEPFAR.org*) has ambitious goals. It intends to: 1) support treatment of two million HIV-infected patients; 2) nurture programs that will prevent an estimated 12 million new infections, and, 3) contribute to the care of 10 million patients infected or affected by HIV/AIDS. The PEPFAR program is operating in 15 countries, most of which are in Africa.

Significance of Funding

There is positive news for the laboratory profession in the Congressional authorization of the PEPFAR II. When PEPFAR I was initially conceived and launched in 2003, funding for laboratory testing was meager, at best. As a consequence, health care professionals in these developing countries—lacking more sophisticated laboratory testing capabilities available to clinicians in developed healthcare systems—had difficulty identifying the patients who were HIV positive and managing the care of these patients.

About 18 months after the program began, PEPFAR leadership recognized that laboratory standards in these countries needed to be enhanced and capable of operating the instrumentation used in monitoring HIV/AIDS patients. "In July 2004, the CDC approached ASCP and asked for assistance developing training materials for laboratorians in PEPFAR countries and providing training in country," recalled Hoffman. "It was envisioned that the training would enhance basic laboratory operations, which would ultimately improve the quality and reliability of the HIV/AIDS patients' results, a goal to which every laboratorian aspires. ASCP was honored to be considered for this project and has been involved since 2004."

Since then, ASCP members and staff have travelled extensively throughout Africa, Guyana, and Haiti to support the training and technical assistance programs under PEPFAR. "This training and support has produced substantial improvements in the practice of laboratory medicine in these countries," commented Hoffman. "It has provided these laboratorians with information and access to lab expertise to which they previously had little or no access.

90 Laboratory Consultants

"ASCP supports a pool of 90 consultants in laboratory services who are members of ASCP. These individuals travel regularly to PEPFAR countries in Africa and elsewhere," noted Hoffman. "There are three project managers who each travel six to eight times a year to Africa, Guyana, and Haiti."

For PEPFAR II, ASCP volunteers will provide assistance to laboratorians in Botswana, Ethiopia, Kenya, South Africa, Lesotho, Côte d'Ivoire, Guyana, Haiti, Mozambique, Namibia, Rwanda, Swaziland, and Tanzania. Experienced laboratory professionals wishing to participate in these activities should contact the ASCP or other laboratory associations involved in PEPFAR activities. TDR

Contact Barbara Hoffman at 312-541-4964 or Barbara.hoffman@ascp.org.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Here's an interesting quirk. It seems none of the major lab professional associations and societies have yet to alert their members to last week's national news about inaccurate Vitamin D test results at **Quest Diagnostics Incorporated.** At least, that was true today, based on visits to their Web sites before this issue of THE DARK REPORT went to press. Among the lab industry trade magazines, only *Clinical Lab Products* had a post on its Web site about inaccurate lab tests at Quest Diagnostics.

ADD TO: Lab News

This may illustrate why the laboratory profession continues to lack the unity found in many other fields of medicine. Because so many lab professionals tend to be most active in medical societies and associations that are connected to their sub-specialty interest, it means lab news tends to flow rather easily within these specialized interest silos, but travels much slower between these silos.

DOUBLE-DIGIT GROWTH AGAIN AT BIO-REFERENCE

Bio-Reference Laboratories Inc. (BRLI), of Elmwood Park, New Jersey, continued its unbroken, multi-year streak of reporting double-digit growth in specimen volume and revenue. Led by gains in esoteric testing, BRLI reported that its fourth-quarter fiscal 2008 earnings surged 12.9%. For the year, the company's net income increased 11.9% to $15.62 million, compared to $13.96 million in fiscal 2007. Total revenue in 2008 grew 20.2%, to $301.07 million, compared to $250.43 million in fiscal 2007. There was also double-digit growth in the number of patients served, which increased 11.0%, to 4.09 million during 2008, compared to 3.68 million in 2007.

BIOIMAGENE SELLS 100 DIGITAL PATHOLOGY SYSTEMS

BioImagene, Inc., hit its goal of selling 100 digital pathology systems in a single year. The Cupertino, California-based firm doubled its business volume compared to the previous year. It shipped 50 scanners in the fourth quarter alone. Using BioImagene systems, the company reports that client-pathologists scanned and analyzed 25,000 anatomical pathology slides in the fourth quarter. The growing numbers of digital pathology systems sold each quarter is one sign that more pathology groups are taking active steps to introduce digital pathology solutions into their daily routine.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know that...

...the job of lab scientist ranks number five on the list of the ***"10 Germiest Jobs in America."*** *That's according to Charles P. Gerba, Ph.D., a microbiologist at the* ***University of Arizona*** *in Tucson.*

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 2, 2009.