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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

Did Theranos Turn Over Its CLIA Lab Director?

PROBABLY NO SINGLE LAB INDUSTRY STORY OF THE PAST 24 MONTHS has generated a higher level of curiosity among pathologists and lab administrators than that of **Theranos**, the Palo Alto, California-based company that regularly claims it has the technology, the business model, and the low price strategy needed to disrupt the clinical lab testing marketplace.

Not surprisingly, within the profession of laboratory medicine, there are many pathologists and laboratory scientists who want to know more about the company's proprietary diagnostic technology. Because the clinical lab profession is such a small community, these "Theranos watchers" are sharing information about the lab company at meetings and on lab bulletin boards.

This information is a pastiche of known facts, leavened with speculation that may or may not be informed. One factor working against Theranos' desire to control all information about the company is the close-knit scientific community of pathologists. Everyone knows everyone, so to speak. It is these personal relationships that are the source of a rumor about how, in the past month, the pathologist who was the medical director on the Theranos CLIA certificate (believed to be the Palo Alto lab facility) has left the employ of Theranos. Individuals claiming to know about this situation said that, after leaving Theranos, this individual did *not* go directly to a new position.

Given the nature of pathologists to have well-organized lives, including not leaving one job without having a new job ready, the pathologists who are aware of this transition have an interesting hypothesis. They point out that, if Theranos asked this CLIA medical director to approve policies or lab testing practices that this pathologist believed to not be in accordance with federal and state regulations, this could be a reason why the company and the pathologist decided to terminate the relationship.

Because of non-disclosure agreements that Theranos vigorously enforces, if this pathologist's medical directorship did end, the truth of the matter is not likely to be known. But should elements of this rumor be true, then one speculation is that the termination might point to possible tension between the business objectives of Therano's owners and how the pathologist-medical director wanted to operate the clinical lab in conformance with federal and state laws. Whether the rumor is accurate or not, one thing is true: neither party is talking! TDR

Pathologists Exploring Use of Diagnostic Teams

Diagnostic management teams bring together pathologists and treating physicians

CEO SUMMARY: In the search for ways to add more value to lab testing services, pathologists and lab administrators are considering organizing diagnostic management teams within their hospitals. Such teams focus on complex cases and include both diagnosticians and pathologists. In his pioneering work to develop the diagnostic management team concept, pathologist Michael Laposata, M.D., Ph.D., spoke recently about how such teams improve patient outcomes while reducing the cost of care.

WHEN LOOKING FOR A WAY to deliver more value with lab testing services, a growing number of hospital-based pathologists and laboratory administrators are considering diagnostic management teams (DMTs).

Probably the leading advocate of DMTs is pathologist Michael Laposata, M.D., Ph.D., Chair of the Department of Pathology at the **University of Texas Medical Branch**. For 30 years, Laposata has promoted the benefits of diagnostic management teams at four different hospitals.

During a presentation at THE DARK REPORT'S *Executive War College* in New Orleans last spring, Laposata made a compelling argument in favor of DMTs, saying they can improve patient safety and patient care while at the same time reducing hospital length of stay and healthcare costs.

Under Laposata's definition, a diagnostic management team includes diagnostic specialists from pathology and other departments as appropriate, along with clinical laboratory scientists (medical technologists). A DMT meets routinely to synthesize clinical laboratory results, the results of other diagnostic studies, and the clinical presentation to establish diagnoses in support of the referring physicians, especially in complex cases.

For the labs owned by hospitals and health systems, DMTs offer two benefits. First, they allow pathologists and clinical lab scientists to contribute their expertise in the clinical care provided to the institution's most challenging cases.

Second, the improved outcomes of patients treated by DMTs often can be measured, as can the resulting reduction in

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the cost of care for those patients. Cost reduction may result from shorter length of stay for patients whose cases were handled by a diagnostic management team because the experts reach a diagnosis rapidly.

Shortening Length Of Stay

Specifically, Laposata addressed the issue of length of stay (LOS) and the challenge of attributing shortened LOS to the creation of a diagnostic management team. "Typically, attributing fewer inpatient hospital days to the work of DMTs has been difficult because, while institutions establish DMTs over a number of months, other improvements also are introduced," noted Laposata. "For example, to date, researchers have collected data only to suggest that a relationship exists between using diagnostic management teams for patients with certain diagnoses and reduced LOS."

The expanded use of electronic health records and the explosion of big data in healthcare are two factors that will make it easier to document the value of diagnostic management teams in the two key areas of improving patient outcomes and significantly reducing the cost of care, he said.

"At any hospital or healthcare system, there is the potential to organize DMTs that address specific diseases and health conditions and that generate millions of dollars per year in cost savings," observed Laposata. "At **Vanderbilt University Medical Center**, just four clinical situations were studied and addressed by DMTs. Yet the cumulative savings were $3 million annually! Therefore, it is possible that, given the large number of clinical disorders, much more would be expected as savings for healthcare institutions."

DMTs At Vanderbilt

Laposata was at Vanderbilt before moving to the Texas Medical Branch in the summer of 2014. In his presentation, Laposata reported that Vanderbilt used DMTs to do the following:

- Eliminate unnecessary testing for leukemia, saving $880,000 annually.
- Reduce length of stay for an estimated 200 Vanderbilt patients who have had a pulmonary embolism, saving $2,000 per case for a total of $400,000 annually.
- Boost throughput for oncologists, allowing them to see 1,000 more patients annually, thereby generating a minimum of $300,000 in additional revenue.

"One factor that has held back expanded use of DMTs is gathering the data required to document the overall cost savings to the institution," explained Laposata. "Each such study typically requires dozens of hours to complete.

"However, the data are gradually emerging and that growing body of information consistently shows that use of a diagnostic expert team to help solve complex diagnoses improves patient outcomes and reduces cost," he continued. "This is a predictable answer, and it is evidence that argues that it is time to reduce diagnostic errors and delays by involving diagnostic experts who are familiar with laboratory test selection and test result interpretation.

More Use Of EHRs Is Positive

"The introduction of electronic health records in most hospitals today makes it easier to document the value delivered by a diagnostic management team that is handling complex patient cases," he stated. "These data are needed to show hospital administration that DMTs are delivering improved patient outcomes, reducing the overall cost of care for those patients, and shortening the average length of stay.

"Studies show that the rate of diagnostic errors or delays is somewhere around one in eight to 10 clinical encounters," he said. "Many pathologists who see overutilization and underutilization of laboratory tests believe that this rate is likely higher.

On Diagnostic Management Teams, Physicians, Pathologists Work Together

BASED ON HIS YEARS OF EXPERIENCE in providing clinical pathology consultative services to referring physicians, pathologist Michael Laposata, M.D., Ph.D., believes diagnostic management teams are a necessary solution for the needs of today's healthcare system.

"The concept of a diagnostic management team (DMT) is simple," stated Laposata, Chair of the Department of Pathology at the University of Texas Medical Branch. "It involves bringing together diagnostic specialists from pathology and sometimes other departments on a routine basis to synthesize all the diagnostic information from all sources and establish diagnoses, especially in complex cases.

"Given the complexity of medicine, particularly with the new molecular and genetic tests that are available, DMTs are a powerful way for pathologists and clinical laboratory scientists to apply their knowledge and experience to support clinicians," he continued. "The goal is to improve patient outcomes and reduce healthcare costs."

Physicians and other healthcare providers are the ones to engage the DMT. "As we have organized our DMTs, the process starts when healthcare providers order tests by requesting an evaluation of an abnormal screening test or clinical sign or symptom," stated Laposata. "Upon receiving that request, the expert physician and colleagues in the DMT evaluate all the clinical and laboratory data and provide a narrative interpretation based on published medical evidence or institutional best practice. This diagnostic information is provided not only when specifically requested by the referring physician—which is typical for clinical pathology—but for every case the DMT handles."

Laposata did want to distinguish a fully-engaged DMT from other types of case review activities. In his view, it is not a DMT activity if any of the following are true:

- The interpretation does not consider clinical information.
- The service does not meet on a regular schedule.
- The interpretation is not written or is not included in the medical record.
- The interpretation is so self-evident that it is not clinically valuable for the treating physician. (For example: The interpretation provides a report only of test results as abnormal but fails to explain why.)

"Whatever the actual rate is for diagnostic errors and delays, increased utilization of DMTs is almost certain to reduce that rate of diagnostic error," noted Laposata. "That is definitely to the benefit of patients and the hospitals treating these patients.

"In a diagnostic management team, pathologists and clinical laboratory scientists have the opportunity to work in close collaboration with the treating physicians to consider all aspects of each patient's case," noted Laposata.

He offered an example of patients on blood thinners. "This is a complex problem," he said. "Most patients who have a stent in one or more coronary artery and are being treated with the platelet inhibitor Plavix to keep the stent open will have great results. But for 20% of all patients treated with Plavix, this drug does not work. Instead, they need an alternative drug that works in a similar way to inhibit platelets.

Helping Docs With Lab Tests

"One way to determine with a laboratory test if a patient will do well on Plavix or need an alternative drug is to do a genetics test," explained Laposata. "But many doctors don't understand 'pharmacogenomics' and so don't know the right lab test to use to determine if patients need an alternative blood thinner.

"So, when considering the approximate $25,000 cost for a patient's readmission due to a clotted coronary artery stent, maybe we should do pharmacogenomics testing for free for every patient about to receive a stent and Plavix," he explained.

"At the outset, this question seemed ridiculous because such testing costs about $300 just for the reagents and supplies!" observed Laposata. "But if this lab test for these patients could prevent 1% (the expected number is as high as 20%) of all adverse events among the 6,400 patients (the number of patients evaluated in a pharmacogenomics study at Vanderbilt) who undergo stenting at a hospital, then we've avoided 60 or so adverse events at $25,000 each. That's a savings of $1.5 million. And the patient has a better outcome! That is far more than the cost of creating a pharmacogenomics laboratory.

Coag-Focused DMTs

"This is an example of where the advice provided by a coagulation-focused DMT supports an increase in the cost of lab tests for these patients in order to reduce the overall cost of care by a significant amount. In the new world of medicine, this is an example of how a DMT can save a bundle of money," he added. "That's a win-win because we improved patient outcomes at the same time."

In Laposata's view, diagnostic management teams are an effective way for pathologists to have an active and ongoing role in patient care in ways that add significant value to the parent hospital or health system. He provided an example of how cost savings can quickly add up to a huge number.

"Let's assume that each of the 150 academic medical centers in the United States could save $50 million annually if they used DMTs for all the diseases they encounter (and most diagnostic errors occur in the commonly encountered diseases)," Laposata suggested. "Now the math becomes interesting because $50 million times 150 hospitals is $7.5 billion.

"Next, there are about 5,000 more smaller nonacademic hospitals where similar benefits are possible and where the advantages of more rapid and accurate diagnoses are not yet appreciated," he continued. "This shows how DMTs have the potential to save billions of dollars nationally while greatly improving patient care." TDR

—Joseph Burns

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New Emphasis on Diagnostic Errors

HEALTHCARE'S NEW EMPHASIS on integrated care presents the pathology profession with a perfect opportunity to expand its role in helping physicians to make more accurate and rapid diagnoses and to aid in the selection of appropriate therapies.

"It is becoming more common for hospitals to be paid on outcomes," stated Michael Laposata, M.D., Ph.D., Chair of the Department of Pathology at the University of Texas Medical Branch. "One example is Medicare's program to reduce hospital readmissions.

"To achieve better patient outcomes, hospital administrators are recognizing the need to foster more integration of clinical care," he said. "Diagnostic management teams are one way to bring together the institution's experts in diagnosis—and that includes pathologists. Take the example of a patient with an undiagnosed bleeding disorder and the large number of lab tests that could be used to diagnose and identify treatment options for that patient. Most physicians don't know how to order the correct tests and interpret test results for patients with such problems.

"Consider the benefit of the diagnostic expert who makes a quick diagnosis, stops the bleeding and saves thousands of dollars in blood products that would otherwise have been transfused," concluded Laposata.

Rheumatologists Oppose UnitedHealth's BeaconLBS

Coalition of State Rheumatology Organizations tells UHC it will 'use all means to resist this policy'

CEO SUMMARY: Yet another specialty society is opposing the laboratory benefit management program UnitedHealthcare introduced in Florida last fall. Rheumatologists have joined four other specialty physicians in saying UHC's BeaconLBS system could be detrimental to patient care. In a letter to UHC, the Coalition of State Rheumatology Organizations said it, "will pursue the reversal of this policy with our state and national societies through every regulatory, legislative, and public means possible."

In Florida, add rheumatologists to the list of physicians opposing **UnitedHealthcare's** implementation of a laboratory benefit management program administered by **BeaconLBS**, a division of **Laboratory Corporation of America**.

In a letter to UnitedHealthcare (UHC), the **Coalition of State Rheumatology Organizations** said it could not support the implementation of UHC's Beacon Laboratory Benefit Solutions system "without data supporting the inappropriate use of laboratory testing by rheumatologists." The coalition also said it "will do all that is necessary to controvert this policy."

Pursuing Reversal Of Policy

In the letter to UHC's National Medical Director, Richard Justman, M.D., CSRO President Michael C. Schweitz, M.D., wrote, "We are going to suggest to our members that they investigate all ethical and legal means to resist this policy and we will pursue the reversal of this policy with our state and national societies through every regulatory, legislative, and public means possible."

The Dark Report recently obtained the letter dated September 11, 2014.

Also in September, in a letter sent to Justman by the **American College of Rheumatology**, Charles King, M.D., Chair of the Committee on Rheumatologic Care, wrote to say the ACR vigorously opposes the approach BeaconLBS takes to managing laboratory test orders.

"The timely diagnosis and safety of patients must not be compromised by ill-advised (albeit well intentioned) systems put in place miles from the patient that subvert or hinder careful decision making by trained clinicians," wrote King. "Often, rheumatologists are the only ones aware of the nuances of their patients' symptoms, disease and needs. Their judgment, expertise and experience simply cannot be replaced by a computer algorithm."

Rheumatologists are at least the fourth specialty society in Florida to complain to UHC about the difficulty physicians are having implementing UHC's new laboratory benefit management program, administered by BeaconLBS. Represented by the **Florida Society of Rheumatology**,

rheumatologists have joined the **Florida Medical Association**, the **Florida Association of Family Physicians**, District XII (Florida) of the **American Congress of Obstetricians and Gynecologists**, the C**ollege of American Pathology**, and the **Florida Society of Pathologists** in complaining to UHC about the onerous nature of the BeaconLBS system.

Some of these physicians have have asked UHC to revise the system or discontinue it immediately and indefinitely, saying it is difficult to implement and could adversely affect patient care. *(See TDRs, July 21, September 2, October 13, November 3, 2014; and January 5, 2015.)*

Pamela Freeman, M.D., President of the Florida Society of Rheumatology, said in an interview with THE DARK REPORT, that rheumatologists have little choice but to use the BeaconLBS system or stop seeing UHC members.

"We have told our members that they have to choose between using the system or dropping out of UnitedHealthcare," she said. "United has threatened to drop physicians from their practice panel or lower reimbursement paid to any physician who does not comply with their Beacon procedures."

Issues Of Appropriate Care

Freeman is part of a three-physician practice in Orlando. She stated that her colleagues have discovered that, when ordering laboratory tests for their patients who have rheumatoid arthritis and lupus, not only does the BeaconLBS system fail to accommodate the required steps, but it takes an excessive amount of time to enter such test orders. "This system is so difficult to use that it discourages physicians from looking for other health problems that our patients have," Freeman said of the BeaconLBS system.

"When we first heard about UHC's laboratory benefit management program, we assumed this would not be an issue for our medical practice," she explained. "We assumed that, because our patients could have their blood drawn in our office or go to LabCorp, we wouldn't need to use the BeaconLBS system to enter all the information needed for the Beacon system.

Use Of BeaconLBS System

"But in fact, to order a lab test on the UHC list, we found we had to enter all the patient's information into the BeaconLBS system," continued Freeman. "This includes the ordering doctor's name, the patient's name, the diagnosis, and the lab test ordered. Moreover, we can't use our electronic health system to enter this information. Instead, we must manually enter this information on the Beacon website."

The requirement to enter lab test order information on the BeaconLBS website means physicians have to enter orders twice, once on the Beacon site and once in their own electronic health record systems. Such dual entry defeats the purpose of the federal government's meaningful use program, which is designed to speed up data entry while making patient information available on a variety of systems.

"When we tried to use the BeaconLBS system, we found it would take several minutes to enter and get the lab test order done," she explained. After complaints to UHC, the insurer conducted a conference call with Freeman and other rheumatologists.

"During the one-hour conference call with the executives at UnitedHealthcare, we had representatives of the American College of Rheumatology and the Florida Society of Rheumatology," stated Freeman. "We presented all the difficulties involved in using the BeaconLBS system, but the UHC representatives said they were not willing to hold up the start date for the Beacon system.

"When it was explained that the medical assistant in our office would not be able to do all the data entry for the BeaconLBS system and keep up with the routine workflow of patients in our office, the UnitedHealthcare representatives sug-

Rheumatologists in Florida Seek Alternatives To Avoid Use of Beacon Lab Test Ordering System

IN FLORIDA, RHEUMATOLOGISTS are looking for ways to continue to serve their patients without having to use UnitedHealthcare's BeaconLBS system.

Rheumatologists say that the BeaconLBS decision support system is time consuming, requires entering data twice, and, most importantly, can interfere with patient care because of the design of its lab test algorithms. But because UHC has required all physicians serving its commercial members in Florida to use the BeaconLBS system since October 1, these specialist physicians have considered different approaches to avoid having to use the BeaconLBS system.

"Some rheumatologists have talked about getting out of the United network, but we don't want to abandon our patients," said Pamela Freeman, M.D., President of the Florida Society of Rheumatology. "Some physicians have suggested another strategy—that they simply stop ordering any of the 80 or so laboratory tests that United says require the use of the Beacon system.

"Not ordering tests would result in a victory for United from a financial standpoint because not ordering tests would cut United's costs," she noted. "But also it would jeopardize patient care because rheumatologists need these lab tests to provide appropriate care to our patients.

"Some rheumatologists suggested another approach," continued Freeman. "They said they will send their lab test orders back to their patient's primary care physicians. That would be one way to avoid using the Beacon system. But it could delay testing and put more of a burden on PCPs and that would not be in the best interest of patients."

gested we do all the data entry for lab test orders at the end of the day," she added. "The problem with that is my medical assistant insists on seeing her children for supper every night. The UHC executives didn't have any answer for that problem.

Staff Overtime Required

"UHC officials said they were willing to listen to problems over time," observed Freeman. "Essentially, that is UHC telling us that 'you must prove that you have a problem,' despite the fact that—at this moment—physicians already have a problem with this system!

"My medical assistant already pulls overtime and UHC has not said it would help me pay for the additional overtime required to comply with this UHC program," she said. "Running the program interrupts physician workflow and causes extra staff overtime.

"In our office we have a medical assistant in the lab," continued Freeman. "We offer phlebotomy for our patients and charge a handling fee for their convenience so that busy patients can get the lab testing done in our in-office laboratory rather than leaving our office to go to a LabCorp patient service center. We must frequently request blood counts, liver function, and kidney tests to monitor patients' medications."

The BeaconLBS system requires physicians serving UHC's commercial patients in Florida to use the system to notify UHC when ordering any of 80 clinical laboratory tests. If physicians do not use the system to notify UHC that they are ordering any of these tests, then the lab that runs these tests may not get paid. The BeaconLBS also requires physicians ordering two tests for breast cancer (BRCA1 and BRCA2) to request preauthorization for these tests. If they do not use the system to request preauthorization, then UHC will not pay the labs that run these tests.

"Many of the 82 tests on UCH's list don't relate to rheumatology, but those

(Story continued on page 18.)

New Service Integrates Pathology and Radiology

UCLA Pathologists, Radiologists Produce Combined Reports

CEO SUMMARY: To simplify diagnostic reporting, the pathology and radiology departments at the David Geffen School of Medicine/UCLA Medical Center are working together to deliver integrated diagnostic information to treating oncologists. This innovative strategy is designed to improve patient care and quality while saving time and cutting costs. For five months, diagnosticians have worked together on more than 50 lung cancer cases while gathering the evidence to show this interdisciplinary approach can improve decision making and reduce downstream treatment costs.

There's a unique and innovative clinical collaboration happening at the David Geffen School of Medicine at the **University of California Los Angeles**. Pathologists and radiologists are working together to develop an integrated diagnostic service.

The value of providing a clinical service that integrates both pathology and radiology services specifically to provide a consolidated diagnostic report to the referring physician has been long-recognized by both medical specialties. But many barriers—mostly institutional—have prevented this concept from becoming a reality.

The Dark Report believes that UCLA is the only academic center in the United States where the departments of pathology and radiology now collaborate to provide integrated reports.

The project is still in the proof-of-concept stage. Further, the two specialty groups have jointly invested their own funds to create a stand-alone diagnostic center that will allow patients to undergo the image studies and provide tissue specimens on one visit. Recently opened, the Diagnostic Center is located next to the **UCLA Medical Center Santa Monica** in a free-standing ambulatory care building.

"Our two departments have multiple goals for this project," stated Scott Binder, M.D., Senior Vice Chair of Pathology and Director of Clinical Services. "We think that combining information from both departments will simplify the reporting for physicians in ways that can improve diagnostic accuracy and shorten the time required for the physician to arrive at the correct diagnosis. We also expect to reduce the discordance when reports are produced independently by pathologists and radiologists.

"This integrated diagnostic service is designed to be patient-friendly and patient-centric," continued Binder. "We eventually want to make it possible for the patient to get all the imaging and tissue collection steps accomplished on one visit to a single site.

"Not only would this be more convenient for the patient, but it would shorten the time required for the diagnosis," he continued. "Our two departments believe that having radiologists and pathologists both available during the collection and imaging stage will raise the accuracy of the resulting diagnosis, lead to a faster treatment decision while producing less expensive care in the long run because cases and procedures will not have to be repeated and because patients will get their results sooner.

More Accurate Diagnoses

"Along with the benefits to the referring physician and the patient, our expectation is that the joint diagnostic service will reduce costs," added Binder. "We expect to realize operational cost savings and we realize that faster and more accurate diagnoses have the potential to generate substantial savings in the overall cost of care for these patients."

According to Binder, the joint reporting system has been in place since September. The integrated diagnostic service has been used for about 50 lung cancer patients.

Binder and colleagues W. Dean Wallace, M.D., Director of Ambulatory Pathology Informatics; and Deiter Enzmann, M.D., Chair of the Department of Radiological Sciences at UCLA Medical Center, are gathering the evidence necessary to show that this system improves patient care while driving down treatment costs, in part by reducing the need for further tests to clarify otherwise uncorrelated and potentially inconsistent findings.

"Our current focus on lung cancer is specifically to help us develop ideas for faster targeting of appropriate therapies for each patient," noted Binder. "We are identifying biomarkers for lung and other cancers, and the number of biomarkers used to identify malignancies is rising all the time.

"Since we began producing combined reports for patients with lung cancer, we've

also begun documenting the data prospectively," said Binder. "This will give us the evidence we need to show if this method of integrated reporting and diagnostic collaboration can have a downstream effect on healthcare quality for patients.

"At the same time, we hope to show that this strategy can improve efficiency and eliminate some of the costs associated with the more traditional approach to diagnostic reporting," he explained.

Binder acknowledged that some medical centers have newer information systems that combine separate reports produced by radiology and pathology. But he emphasized that the radiology/pathology collaboration at UCLA is much more deeply integrated.

"What distinguishes our collaboration is that we share data even before it is time to bring together the reports from radiology, pathology, and any other departments, such as molecular testing," explained Binder. "By sharing the data and developing the reports the way we do, we are confronting occasional discordance between pathologists and radiologists. Confronting and eliminating that discordance makes a significant difference for treating physicians seeking to improve patient care and outcomes."

Significant Benefits Seen

Wallace explained the issue further. "There is great value in producing combined reports as we do it because we can find any discordance before it causes problems," said Wallace.

"In most hospitals, pathologists and radiologists work in separate silos," Wallace continued. "That means pathologists don't know what radiologists have found and radiologists don't know what pathologists have found even when working on the same patient cases.

"Under the current paradigm, let's say an oncologist has a patient with a mass and orders a work up," he said. "That work-up would include a CT diagnostic study with contrast and maybe a PET scan. The pathology work up may include a biopsy and multiple molecular reports.

"As the oncologist gets the results of all these different studies—and there may be five or six or more and they may be in different information systems—he or she has to synthesize all the data from each report," stated Wallace. "And, what if one or more of the reports is missing? The oncologist may not even know what's not there.

Helping The Oncologist

"Further, as the oncologist goes through the different reports, it is possible that something confusing is present in the reports," he continued. "For example, it could be that the pathology report doesn't agree with the radiology report.

"Such discordance is not unusual, and, yet the oncologist may have to wait until the tumor boards—which may not be for a week or more—to get any questions answered," he said. "That is a built-in delay between the time the patient has the diagnostic stage and when the oncologist has a diagnosis and can develop a treatment plan.

"Now consider our system," said Wallace. "We have improved communication among radiology, pathology, and all members involved in the diagnostic work up. For any patient with lung cancer who comes through our system, there is much more email and telephone communication from all the physicians involved in the diagnostic work up. In addition, there is a much better understanding among the pathologists about what the radiologists have found and vice versa.

"In our method, pathologists have a deeper understanding about what's in the differential diagnosis from the radiologists and the radiologists have a deeper understanding about what's in the differential diagnosis from the pathologists," he said. "Under our system, that factor alone can make a big difference in how the case is managed. At the very least, it can speed up the time from work-up to diagnosis.

Personalized Medicine Is Poised to Drive Changes in Both Diagnostics and Therapeutics

FOR MANY YEARS, ALL OF MEDICINE has emphasized therapeutics, said Scott Binder, M.D., Senior Vice Chair of Pathology and Director of Clinical Services at the David Geffen School of Medicine at the University of California Los Angeles.

"In the coming years, within medicine, we may see changes in both diagnostics and therapeutics," he explained. "When pathologists and radiologists work together, they can sample tumors and compare their molecular signatures and adjust a patient's care over time.

"This is how medicine delivers personalized care to the patient," said Binder. "If a tumor becomes less susceptible to a particular drug, we can work with the oncologist to understand why and thus we can prolong life and save lives. Ideally, we hope to prevent the tremendous amount of money that goes into tests for cancer patients and patients at the end of life.

"In the past therapeutics has driven the whole medical establishment," he continued. "However, as we move to personalized medicine, diagnostics may become the chief driver of the healthcare system. That's because diagnostics will identify the most appropriate therapeutics needed for targeted therapies.

"As this occurs, pathologists and radiologists will need to work together more closely to better serve oncologists and other subspecialists," noted Binder. "Certainly pathologists and dermatologists have always worked together and will continue to do so. Today it is possible to envision a combined report that includes gross images from a dermatologist with reporting from a dermatopathologist.

"Interdisciplinary work will not be limited to cancer," said Binder. "It is possible that cardiologists will have pathologists add correlated information to electrophysiology reports. This is just the beginning of a new era in interdisciplinary collaboration and high-value reporting.

"Several vendors are developing systems that will foster interdisciplinary workflow," he said. "Here at UCLA, many potential industry partners are interested in collaborating with us. These companies already have bioinformatic systems and strategic plans to enter this space with systems we can use for data storage. These systems will also have the ability to mine that data to support evidence-based care and best practices by pathologists, radiologists, and others."

"Further, we also add reports from others, such as molecular pathologists, as well as any physicians involved in doing PET scans," explained Wallace. "It is the same if multiple radiologists are involved, such as the radiologist who does the diagnostic study and the radiologist who does the interpretive or interventional study.

"Once all reports come together into one portal, both radiologists and pathologists are compelled to synthesize their data so that the final product has unity and makes sense," he noted. "In other words, the radiology report can't conclude that the patient has a mass when the pathology report concludes that the patient may have interstitial lung disease. That would be discordant."

In the pilot study involving lung cancer patients, the integrated reporting at UCLA involves a different workflow through pathology, radiology, and any other clinical service involved in the diagnosis. It is supported by a customized software system designed at UCLA that is called UCLA RadPath.

"Take the example of a lung cancer patient," noted Wallace. "When the biopsy comes to pathology, the pathologist issues a report and signs out the case. The report goes into the system and becomes part of each patients' medical

record. Then the system takes the primary diagnostic imaging study and combines it onto one page with the surgical pathology report. Also included are the molecular reports and any radiology studies, all of which are accessible by clickable tabs.

"At this stage, all the pathology reports are on the screen," he continued. "I choose the one that best represents the pathologists' finding, and the system starts building the combined report. Once the beginning of the combined report is complete, I can add any other reports, such as from cytology.

Helping The Oncologist

"The cytology report exists as an attachment and displays in a pop up window if needed," he said. "Also, the report includes the cytologist's contact information, thus allowing the oncologist to know who signed off on that portion of the report.

"Once that element of the report is complete, the system extracts images from PowerPath or from the laboratory information system," stated Wallace. "At this stage, the report is ready to go to the radiologist and it is also quite useful as a presentation tool for a tumor board.

"After I sign out the pathology part of the report, I hit 'Finalize,' and the system finds the radiologist who did the biopsy report and sends an email to that radiologist," he said. "Then the radiologist can review the pathology parts of the report and edit the report by adding the radiology reports. He or she then signs off.

"One advantage of this method of working is that it compels the radiologist and the pathologist to address the report before it goes live into the system," Wallace explained. "In that way, it can support the oncologists in their work ups and shorten the time to diagnosis.

'Offline Tumor Board'

"Another advantage of the combined report is that it can serve almost as an offline tumor board," he added. "The combined report is almost as thorough as tumor boards because it contains the diagnosis, the staging information, and the radiology and pathology information in one place."

Binder agreed, saying there are significant advantages in having a combined report. "The report is built by combining the radiology report that is in the radiology information system and the pathology report that is in the LIS," he said. "Once the pathologist reviews the pathology report and signs off, then the radiologist reviews the radiology report and signs off as well.

"For the report to be completed, both the pathologist and the radiologist have to sign out," stated Binder. "That way, if there is any discordance, it can be resolved. Both physicians have the option to resolve it or they can explain why there is discordance.

"At that point, the radiologist can enter a correlation statement, if needed, at the top of the report," he continued. "In the correlation statement, the radiologist addresses whether the findings correlate or not. If they do not correlate, the radiologist can explain why."

Addressing Discordance

Wallace added that, where there is discordance, the radiologist can add one of four correlation comments. "One of the choices is that the findings correlate; another is that the findings do not correlate and the radiologist defers to pathology; a third is that there may be a sampling error or some other reason; and the fourth is that the findings do not correlate and the pathologist defers to radiology," he said.

"The correlation comments add more nuance to the report than you would get with two separate reports (one from pathology and one from radiology) and this is why our combined report is more helpful to the oncologist," Binder added.

"For example, we had a case in which a lesion was in a difficult location and the correlation comment was 'Consider a thoracic surgery consult,'" he noted. "These comments help provide not only a deeper

understanding of the diagnostics but also can help guide the oncologist to the next step."

After five months of developing this new way for diagnosticians to collaborate with each other and with oncologists treating patients, Binder, Enzmann, and Wallace are still fine-tuning the system. "It is live for any case of lung cancer but we are still optimizing its use to assess the length of time it takes to work up these cases and produce reports," Wallace said.

"One survey we did produced positive results, but there are still some issues we need to resolve before saying it is fully ready," he noted. "Even in the beta stage, it's an important development for the UCLA Medical Center and it has the potential to improve care across the country."

Binder agreed, saying the next step is to collect and publish the data needed to demonstrate its utility to physicians and payers. "The only way this will catch on is if we can prove that it has value. Then Medicare and others will consider it," he said.

"Currently, for these cases, radiology bills separately and pathology bills separately. But medicine almost certainly will develop more interdisciplinary relationships and pathology and radiology are obvious disciplines to work in this way.

Interdisciplinary Interaction

"Here at UCLA, the departments of radiology and pathology hope to demonstrate that our interdisciplinary interaction will achieve improved value," stated Binder. "When it does, we expect this kind of interaction will guide future reimbursement because we hope to be able to show that pathology and radiology can collaborate in ways that boost quality, improve patient outcomes, and reduce costs." TDR

—Joseph Burns

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Informatics Capabilities Enable Collaboration

FOR ALL THE ADVANTAGES of producing reports that combine data from radiology and pathology, pathologists may wonder why more medical centers haven't developed such systems previously.

"The reason is that information systems are just now becoming sophisticated enough to make such combined reporting possible," observed Scott Binder, M.D., Senior Vice Chair of Pathology and Director of Clinical Services at the David Geffen School of Medicine at the University of California Los Angeles.

"Bioinformatics has taken on a bigger role in all of medicine and both radiology and pathology have sophisticated bioinformatics departments," he said. "The systems we use today at UCLA allow us to collect and store the data we generate from cancer patients so that we can follow them prospectively while also considering many different treatment variables.

"With these bioinformatics systems, it will still take many years until we know that this method of collaborating and reporting has had a positive effect on patient care and on costs," noted Binder. "That is why we selected lung cancer for our first integrated diagnostic service involving pathology and radiology.

"Given the types of lung cancer we see, we will know within a couple of years how the patient has done and we can compare those outcomes to the outcomes of patients who had more traditional treatment," he stated. "We expect to have a very sophisticated and useful data set that will prove the utility of these combined radiology and pathology reports both in terms of quality and also in terms of saving money downstream.

"We won't see the results immediately," concluded Binder. "We expect to see the total value of what we saved downstream in terms of cost savings and improved quality. That's what will take a number of years to evaluate."

Meaningful Use Stage 2 Is Problem for EHR Firms

➤Many smaller EHR companies are struggling to meet meaningful use rules; some won't survive

➤➤CEO SUMMARY: EHR system vendors must now comply with the federal government's Meaningful Use Stage 2 requirements. Well-established EHR vendors will survive. But smaller EHR companies may struggle to provide the enhancements to their first generation EHR products that are required to certify as MU Stage 2 compliant. These developments mean many physicians may need to find new EHR vendors. In turn, that will require clinical labs to build new interfaces to these physicians' EHRs.

IN A TREND that has important consequences for many clinical labs and pathology groups, a significant number of EHR vendors are going out of business as they find it difficult to comply with the federal government's Meaningful Use Stage 2 requirements.

"When EHR vendors go out of business, physicians using those EHR products and who want to continue using an EHR will need to go shopping again to select a vendor that complies with MU Stage 2," stated Pat Wolfram, Director of EMR and Lab Integration for **Liaison Healthcare Informatics** in Alpharetta, Georgia. "Once that happens, clinical labs need to build new LIS-to-EHR interfaces in order to maintain the flow of lab test requisitions from those physicians."

Because of this problem, for the second time in recent years, some labs find themselves building another interface to physicians forced to buy and install a second EHR. "Achieving MU Stage 1 compliance was relatively easy for EHR vendors," explained Wolfram. "But meeting Stage 2 requirements is proving both complex and expensive for EHR vendors and that is causing some EHR companies to simply go out of business.

"The certification numbers tell part of the story," he noted. "In 2011, the number of certified ambulatory 'complete' EHRs was 1,956. Last year, that number was down to only 547.

"Many small EHR companies have limited revenue and resources, making it impossible for them to get their Stage 1-compliant EHR systems to meet the Stage 2 requirements, for three reasons," Wolfram explained.

➤Struggle for Some EHR Firms

"First, when an EHR vendor wants to certify its EHR system as being Stage 2 compliant, it must put substantial development, quality assurance, and documentation resources into the process," he said. "It's a significant expense for some of the vendors. Second, the features required in MU Stage 2 are much more complex. This makes it harder for EHR vendors to develop, test, document, and train users compared to MU Stage 1 requirements.

"There is a third factor that every new software vendor has to address: the EHR system must complement physician workflow," noted Wolfram. "To do that job well, the EHR vendors must master clinical workflows and enable the secure and convenient management of chart data. Clinical content must be easy to record in the EHR.

"Further, the EHR system must store clinical content securely, allow it to be accessed only by authorized users, and then make such data reportable in a manner that helps with disease management and illness trending," he added.

Wolfram identified a related problem. "Some of the larger EHR vendors have accumulated multiple EHR products through mergers and will not continue to support them all," he observed. "And even though they provide a migration path from the sunsetted EHR to one that the vendor is supporting, it still means a new EHR for some practices, something new to learn, and a new interface for a lab to build. There are cases where the practices are deciding to go EHR shopping again, instead of defaulting to another EHR from their original vendor.

"Because far fewer EHR vendors will comply with MU Stage 2, labs face both a new cost and a potential opportunity," noted Wolfram. "The new cost is that physicians will be selecting a new EHR vendor and labs will need to interface to those systems. That will be both expensive and time-consuming for labs.

"On the other hand, this is also an opportunity for labs," he continued. "Labs now have experience with multiple EHR products, so they can advise physicians on which EHR vendors have solid lab integration capabilities. Most physicians assume an EHR can integrate well, but that's not always the case.

"When a client physician is considering that next EHR, the lab should step forward and share its experience gained from writing LIS-to-EHR interfaces with different EHR systems," advised Wolfram. "In these situations, the lab has credibility because it is already working with different EHR systems. Physicians who want to get it right with a second EHR purchase will listen to their laboratory's recommendation on these points." TDR

—Joseph Burns

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LIS-to-EHR Interface Checklist of Features

ANY CLINICAL LABORATORY receiving lab test orders from physicians may want to advise physician clients on which EHR features are important to evaluate, said Pat Wolfram, Director of EMR and Lab Integration for Liaison Healthcare Informatics. To do so, physicians should ask questions to help determine if the EHR vendor will provide a product that can meet Meaningful Use Stage 2 and support the business for the long term.

Here are the questions:

- MU Stage 2 requires physicians to record lab orders in the EHR chart record. Is it easy for the physician to record diagnostic tests?
- MU Stage 2 requires that numeric lab results import as structured data to the patient chart. Can the vendor demonstrate this feature?
- Does the EHR have its own result code database, such as LOINC? If so, the lab or clinic must be prepared to cross map the lab result codes to the codes of the EHR.
- Can the EHR vendor show how it handles lab results that don't match to the patient's chart?
- Must an EHR's imported lab result be associated with an order from that EHR? If yes, then the EHR will have trouble supporting unsolicited lab results.
- Can the EHR import a clear and understandable lab report? In particular, make sure the clinic evaluates the clarity of pathology and microbiology lab reports. If these are not satisfactory, then can the EHR import a lab report in PDF format?

(Story continued from page 9.)

that do are important for our patients," noted Freeman. "Examples are tests for ANA (antinuclear antibody) and vitamin D testing. We need to run both of these for our patients in a timely fashion."

"We use the antinuclear antibody test to help diagnose a suspected autoimmune disorder," she said. "Similarly, with our patient population, vitamin D often needs to be assessed to ensure the level is adequate. If it's not adequate, then the supplement dose must be changed. Many patients in Florida are vitamin D deficient."

Problems With Algorithms

Freeman next pointed out that lab test pre-notification algorithms within the BeaconLBS system create their own problems and could negatively affect patient care. "What does a rheumatologist do when monitoring a patient and learning that a condition has changed, such as for vitamin D levels?" she asked. "When you order a vitamin D test, BeaconLBS asks you to answer two questions. The first question: 'Is this test to diagnose vitamin D deficiency?' But what does that mean? Do we already know it's deficient or are we trying to find out?

"The next question in the BeaconLBS system has more than a dozen subparts to fill out, including demographics of the patient, ethnic background, and the patient's diagnosis, including osteoporosis. It looks like the BeaconLBS algorithm wants to know if there is a reason to order the lab test.

"But what about recent research showing that adults and children with lupus—who are vitamin D deficient—don't do as well as those who have sufficient vitamin D? That clinical study indicates that we should check the vitamin D level for lupus patients. But, in BeaconLBS, that's not one of the boxes to check. The algorithm does not address all the reasons a rheumatologist would order a vitamin D test," she concluded. TDR

—Joseph Burns

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Rheumatology Groups Send Complaints to UHC

IN LETTERS TO UNITEDHEALTHCARE, the presidents of two groups representing rheumatologists in Florida criticized UnitedHealthcare's pilot laboratory benefit management program and the BeaconLBS system that is part of the program as having the potential to negatively affect patient care.

BeaconLBS is a decision support system for lab test ordering that UHC says all physicians must use when ordering any of certain lab tests for its commercial patients in Florida.

"This policy will create an administrative burden on practicing rheumatologists, requiring the devotion of time and resources by the physicians and their staffs to obtain the authorization necessary to have certain rheumatologic tests performed," wrote Michael C. Schweitz, M.D., President of the Coalition for State Rheumatology Organizations. "Requiring trained certified specialists to obtain authorization from a less qualified person or entity using a rote, inflexible algorithm is not only unnecessary but insulting."

In a letter from the American College of Rheumatology, Charles King, M.D., president of ACR's Committee on Rheumatologic Care, explained that the BeaconLBS system requires physicians to enter lab test orders twice. "Requiring clinicians and their staff to leave a patient's chart, access a separate portal, and obtain prior authorization to order a test, all post obvious barriers that will, predictably, increase administrative costs for practicing clinicians. But any barrier that prevents appropriate laboratory testing will also increase costs in other ways, many of which will be borne by payers," he wrote.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Interesting things are happening in the commercial clinical lab testing market internationally. In New Zealand, district health boards continue a decades-long trend of squeezing commercial lab companies with the goal of reducing laboratory testing costs and eliminating redundancies. Currently the district health boards (DHBs) of Capital Coast, Hutt Valley, and Wairarapa—representing the the lower part of New Zealand's north island—are evaluating proposals to consolidate all community and hospital laboratory services into one service entity. Newspapers report that the DHBs want "one management structure and process across the region." News reports also say that the DHBs are in talks with two private lab companies: **Aotea Pathology** and **Southern Community Laboratories**.

ADD TO: *Global Labs*

International Diagnostics Holdings, a lab company based in Egypt, intends to offer an initial public offering (IPO) on the London Stock Exchange in February. The company plans to raise up to US$300 million by selling 45% of the company. The company says it offers genetic tests, diabetes diagnosis and basic radiology across seven different brands, four central labs, and 283 branches across the Middle East. Integrated Diagnostics was formed in 2012 by the merger of **Al Mokhtabar** and **Al Borg Laboratories**.

TRANSITIONS

• **Aurora Diagnostics** of Palm Beach Gardens, Florida, announced the appointment of Anthony Bobos as Chief Information Officer. Bobos was formerly with the **BloodCenter of Wisconsin**.

• Jennifer Skeen, Ph.D., is the new Vice President of Clinical Operations for **bioTheranostics, Inc.**, of San Diego, California. Previously she held management positions with **Pathway Genomics**, **Asuragen**, and **Alverno Clinical Laboratories**.

• Sue Beruti, M.D. has joined bioTheranostics as Medical Director. Beruti formerly held executive positions at **Genoptix**.

• Thomas McKee Williams, M.D., died on January 7 at the age of 57. He was the Chair of Pathology at the **University of New Mexico** Department of Pathology from 2008 through 2012 and a former Executive Vice Dean of the **UNM School of Medicine**.

That's all the insider intelligence for this report. Look for the next briefing on Tuesday, February 17, 2015.

SPECIAL SESSION!

TriCore's Transition from Volume to Value: Creating New Revenue Streams by Delivering Clinical Intelligence to Physicians & Payers

Khosrow Shottorbani
CEO, TriCore Reference Laboratories,

How Matching Lab Data with Healthcare Big Data Positions Clinical Labs To Influence Outcomes, Costs

For years, pathologists have regularly pointed out that clinical laboratory data is an ideal point of leverage to accomplish three things: improve patient outcomes, boost the quality of clinical care, and significantly drive down healthcare costs. Leadership at TriCore Reference Laboratories agrees... and is ready to blaze a new trail!

TriCore already produces 70% of all the clinical lab test data within New Mexico. It is now partnering with such entities as SalesForce.com to pool its lab test data with other clinical information, then use advanced informatics to provide clinicians with real-time, actionable intelligence.

Outbreak of the flu in Santa Fe? TriCore has the capability to alert physicians in that area to this fact in its earliest stages, along with guidance on how to utilize the right lab tests as patients show up. This is one example of the bold new frontier for clinical pathology consultation now unfolding at TriCore Reference Laboratories! Be with us for this exciting session!

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UPCOMING...

- ***Hospital Mergers and Health System Acquisitions Fuel a New Wave of Hospital Lab Consolidation.***
- ***Challenges and Opportunities for Specialty Labs: Why the Market Is Rewarding Some Lab Firms.***
- ***New Ways to Unleash the Power of Lean to Slash Costs while Boosting Productivity.***